EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE NO. 2:12-MD-02327 MDL NO. 2327
THIS DOCUMENT RELATES TO ALL WAVE 4 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS: Rebecca Melton CASE NO. 2:12-cv-04094	:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

Transcript of deposition of BRIAN D. PARKER, M.D., taken by Charlene M. Shade, LCR, Notary Public, at the Hilton Garden Inn West, 216 Peregrine Way, Knoxville, Tennessee on Tuesday, March 14, 2017, commencing at 8:30 a.m.

APPEARANCES:
ON BEHALF OF THE PLAINTIFFS:
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLC
BY: D. RENEE BAGGETT, ESQUIRE
17 East Main Street
Suite 200
Pensacola, Florida 32563
850.202.1010
Rbaggett@awkolaw.com

ON BEHALF OF THE DEFENDANTS:
BUTLER SNOW
BY: JORDAN N. WALKER, ESQUIRE
Renaissance at Colony Park
1020 Highland Colony Parkway
Suite 1400
Ridgeland, Mississippi 39157
601.948.5711
Jordan.walker@butlersnow.com

I N D E X

E X H I B I T S

(Time 8:30 a.m.)
BRIAN D. PARKER, M.D.,
having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. BAGGETT:

Q. Good morning, Dr. Parker.
A. Good morning.
Q. Could you please state your full name for the record.
A. Brian David Parker.
Q. And can you tell us where you're working currently?
A. Tennessee Urology Associates.
Q. And how long have you been with them?
A. Since 2005.
Q. And when did you first become associated with Ethicon with regards to this litigation, if you recall?
A. Around November of 2016.
Q. And what capacity was that in initially?
A. What capacity?
Q. Was it preceptor? Was it --
A. No. No. It was only for the purpose of being an expert witness.

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Q. And have you served as an expert before?
A. No.
Q. Have you been involved with Ethicon in any other capacity as a consultant?
A. No.
Q. In looking at your CV, I saw that you may have been involved with another device manufacturer. What other manufacturers have you been involved with consulting?
A. With Galil Medical. They have a cryoablation machine for malignancy. I'm a proctor for Medtronic and for Coloplast. I'm a proctor for their Altis line.
Q. How long have you been a proctor for Coloplast?
A. Well, probably three years, but, honestly, I've only proctored a few times. Yeah, probably about three years.
Q. And how long have you been performing procedures that include vaginal mesh products?
A. Since residency, so that would be somewhere around two thousand and -- no. Let's see. Yeah, probably around 2001, 2002.
Q. Do you recall what the first mesh product was that you were familiar with?
A. The TVT retropubic.

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Q. And were you trained in residency on how to use it or did you attend classes that were held by Ethicon?
A. I trained in residency.
Q. And were you provided materials during that training period, do you recall?
A. That's been a long time since then, so I don't recall any materials, no.
Q. Would you have seen the IFU, for instance, potentially in your --
A. In residency?
Q. In training.
A. In the training for TVT retropubic?
Q. Yes, sir.
A. No.
Q. Have you ever been deposed before today?
A. Yes.
Q. How many times?
A. Twice.
Q. In what capacity were you deposed?
A. Malpractice case.
Q. And were you a witness or were you a party?
A. A party.
Q. And we don't have to go deep into details,

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but if you could give me some idea what those cases were about.
A. It was the same case, and I had to be deposed twice because it went to mistrial, and it was about a surgery for renal cell cancer. We were found not guilty, but that process took three or four years.
Q. So you're somewhat familiar with the deposition process?
A. A little bit.
Q. The main rules, obviously, are to have speaking responses, no nodding of the head. Let me finish my question so that we don't talk over each other and --
A. Okay.
Q. -- I'll try to do the same for you. I know time is short, and as we get closer to the end of my time, I talk a lot faster. I don't do that to mean any disrespect, but we are limited on what time and there's a lot, as you know, to be covered under these circumstances.
A. Uh-huh.
Q. I was provided some invoices. Let's go ahead and take care of a couple things before we move to that, though.
I'm going to hand you what's been marked as Exhibit 1. This is the notice of deposition in this case.

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(Exhibit 1 - Deposition Notice)
A. Yes.
Q. And I wanted to ask if you recall seeing that before today.
A. I have.
Q. And if you'll turn toward the mid section, I think it's entitled Schedule A.
A. Uh-huh.
Q. Have you seen Schedule A before today?
A. I scanned through the first few pages. I don't know that I've read through every bit of it, but I did look through some of this. Schedule A. Okay. Yes.
Q. And the Schedule A is a request for the production of documents and things, and I noticed that you've brought both a book binder and a thumb drive. So are those materials brought in response to Schedule A?
A. Yes.
MR. WALKER: Let me interject and state for the record, we have brought a thumb drive and the thumb drive contains all of his general reliance materials.
MS. BAGGETT: Okay. You can put that aside for now. And we're going to mark for Exhibit 2 the expert report that you prepared in this matter.

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(Exhibit 2 - Expert Report Of Dr. Parker)
MS. BAGGETT: And we'll go ahead and mark as Exhibit 3 the CV.
(Exhibit 3 - Curriculum Vitae)
MS. BAGGETT: And 4 and 5 will be your general reliance list and your supplemental reliance list. And I wanted to do that before I got ahead of myself and forgot to do so.
(Exhibit 4 - General Reliance List)
(Exhibit 5 - Supplemental Reliance List)
MS. BAGGETT: I'm going to also go ahead and mark as -- I think the last exhibit was Exhibit 5?
MR. WALKER: Yeah.
MS. BAGGETT: As Exhibit 6 we'll mark your invoices.
(Exhibit 6 - Invoices Of Dr. Parker)
MS. BAGGETT: Exhibit 7 will be your binder.
(Exhibit 7 - Exhibit Notebook Prepared By Defendants)
MS. BAGGETT: And Exhibit 8 will be the thumb drive.
(Exhibit 8 - Thumb Drive - Reliance Lists)
BY MS. BAGGETT:

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Q. Okay. Turning to your invoice -- and I'll pass it back to you if you need to refer to it, but I'm just going to ask you generally about it.
It appears that, if my calculations are correct, you spent about 160 hours or so on this project. Does that sound right?
A. That sounds right.
Q. Okay. And -- well, I'll let you just tell me what some of those things consisted of, and you can use the document to refresh your recollection.
A. Okay.
Q. What did you do to prepare to draft the report in this matter?
A. Well, you know, the first thing I had to do was get an overview of -- or meet Jordan, so there was some time we had to meet. And then I did quite a bit of review of the medical literature. Some was supplied by Ethicon, a lot of it was on my own. I went back and reviewed the company documents, did a lot of thinking, a lot of pondering, did a lot of -- went back and looked at some of the previous depositions, experts and plaintiffs on both sides. Wrote the general report.
Q. Okay. I know that's a lot. That's a very broad question.
How much time did you spend, would you

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estimate, doing your own research?
A. At least 30 hours.
Q. What type of research did you do? What type of search did you perform?
A. Well, PubMed searches, of course. You know, I had some of my own, you know, old journals, reviewed those. Some of the stuff from textbooks, chapters that had been written in the past. So just a conglomeration of a lot of things. The majority of it was probably PubMed, you know, on-line research.
Q. How much time would you estimate that you spent reviewing materials that were provided to you by Ethicon?
A. I'm going to say probably the same amount, if not more. Maybe 40 hours, probably.
Q. And in reviewing the materials that were supplied to you from Ethicon, did you look at every document that was supplied to you?
A. I made a good effort. I mean, you can ask my wife; I wasn't around a whole lot. I mean, I spent a lot of time reviewing everything I could. Could I remember everything? Probably not right now, but I tried.
Q. But you think you've at least put your hands on everything that was in your reliance list?
A. Some form or another. There may be areas

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I may not have been able to get all of, because that was a large amount. There was a lot of volume of this. I may not have seen every little bit of everything, but the majority of it I did.
Q. So each one of the -- if you want to take a look at the first reliance list. Can you tell me if you know the difference between what was in the first reliance list that is different to what was added -- or I got that backwards.
Can you tell me what was added to the supplemental reliance list that is different to what was originally submitted in the --
A. Yeah, I think those would be the things that I've -- some of the on-line things that I did that I needed the full articles pulled on. Some extra -- you know, as new studies come out, getting the new studies, those type of things.
Q. And did you compile the reliance list yourself?
A. No, I didn't type this up.
Q. And did you have any -- did you offer any assistance with the supplemental list?
A. Yes. I didn't type it up, but, again, I did want to make sure I had everything in there.
Q. And I think you've mentioned that you read

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some depositions and maybe you said -- maybe I may be misstating, but did you also review the expert reports in this case by other experts?

A. Yes.

Q. Do you recall which expert reports you read?

A. I remember Rosenzweig I think. Is that one of the guys? That sounds familiar. Sepulveda maybe. Honestly, I can't remember the names of the others. I'm sorry.

Q. That's okay. Did you rely in any way on the information you read in these reports?

A. Did I rely on it?

Q. Yes, sir, or any of them. Were there any reports that you read that you relied on in drafting your own report?

A. Well, I relied on everything I read, and that was part of it. And it helps in a way that -- you know, you want to take an objective view of this as best you can, and so one way you can do that is by seeing both sides of the story. And so, yes, it's all part of my mental formulation of things.

Q. Let's jump over to your background with the sling usage, and you've already told me that you learned about the TVT product when you were in residency --

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A. Yes, ma'am.

Q. -- back in approximately 2005, did you say? 2002?

A. 2002. Yeah, that would be about right.

Q. Did you begin immediately implanting devices after your initial training?

A. Yes.

Q. Did you continue to use the TVT device as your primary device that you implanted?

A. No. TVT obturator.

Q. And so if I understand, you were trained on the TVT-R. Were you at some point also trained on the TVT-O?

A. Yes.

Q. And when was that approximately?

A. 2004, 2005.

Q. And after being trained on both of the products, you chose to continue to implant the TVT-O; is that correct?

A. Yes, ma'am.

Q. And what were your reasons for wanting to use the O versus the retropubic?

A. I feel like it was -- I was getting good results. I felt like it was something that was pretty straightforward as far as placement of it. I wasn't seeing

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a lot of problems with it. And I felt like that I could have less -- I feel like by doing the TVT-O I could really treat most of my patients satisfactorily with that.

Q. How many TVT retropubic devices would you estimate that you've implanted in your --

A. Retropubic?

Q. Yes.

A. Less than 20.

Q. And maybe -- I think it is in your report, but can you tell me approximately how many TVT-O devices you've implanted?

A. Around 200, I would suspect.

Q. Other than the TVT-R and the TVT-O, were you trained on any other devices?

A. Yes. Monarc, SPARC. I can't remember all the names of them, but through residency, as far as, you know, devices, we did pubovaginal slings, Burches, the whole gamut of things, but I can't remember all the names of them. They all had specific names, but I can't remember all the names of all the different products. But the guys I trained with were very open -- because that was kind of the beginning of all these slings, is they really wanted to see the difference in the different material, the different slings, the different placement. So, yeah, I got a good experience in residency with those.

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Q. After you learned to use each of these other devices you mentioned, did you also use any of those devices in your procedures treating your patients?

A. I'm sorry. Say that again.

Q. I want to find out if you ever implanted any of these other devices into patients you were treating.

A. Out of residency? Like in practice or in residency?

Q. Just in general. At this point I'm just wanting to see how many different devices that you've implanted in --

A. Honestly, I don't know that I can give you a number because there was just a small sample size of each one, and so I don't really know. The majority of what we did, after a period of time, was either retropubic or TVT-O in residency.

Q. Is it fair to say that of those other devices, you learned enough to decide whether or not you wanted to use them and went with something that you were more comfortable with?

A. Yeah. I mean, for better or worse, I mean, that's -- you have to make a decision, right?

Q. Right.

A. And so that was the one that I felt the most comfortable with.

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Q. Do you recall any of the other qualities of those devices that may or may not have been as appealing to you as a surgeon performing these procedures?
MR. WALKER: Object to form.
A. I mean, the only one that I felt -- no, there was nothing uncomfortable. There was nothing really, like I say, that didn't jibe with my skill set. It was really just needing to pick something I felt comfortable with, had some durability, had some long-term results, there were some studies on. And so that's what eventually led to my decision to continue to pursue that.
Q. Do you still continue to implant the TVT-O device today in your practice?
A. No.
Q. What device do you implant today?
A. Altis slings.
Q. I'm sorry?
A. Altis by Coloplast.
Q. Do you recall when you switched to the Altis device?
A. After Secur got off the market.
Q. Approximately when did you begin implanting the TVT-Secur device?
A. When it came on the market. Well, let's see. It was going to be probably around 2007 when I

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started implanting that.
Q. And when you were trained on the Secur device, were you trained in your residency or was this something --
A. It wasn't done in residency. It was trained by a proctor.
Q. So someone with Ethicon?
A. Yes.
Q. Do you recall who your proctor was?
A. Yes.
Q. Who was your proctor?
A. Dr. Christopher Ramsey.
Q. How long did you train on the TVT device before you began implanting?
MR. WALKER: Object to form. Which TVT device?
BY MS. BAGGETT:
Q. Other than Secur. I'm sorry.
A. How long did I train? I don't recall exactly. I do remember there was kind of a step-wise approach I went through. I mean, I observed him putting in some, watched a video, read material, was then proctored on, I would say, somewhere around five cases of my own until the proctor felt like I had the technique down.
Q. And when you implant a mesh device, how

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long do you generally follow up with your patients?
A. Usually see them at six weeks and then the majority of them I see in six months, a year, oftentimes, you know, many years afterwards. It seems to me that if the patient is doing well, they'll miss their appointments, but we try to get them back in to see how they are doing.
Q. What's the longest you've followed a patient that you've implanted a sling device in?
A. What's the longest?
Q. Yes.
A. Oh, I had a patient the other day I implanted in 2005, right when I got in residency. So it's been however many years now, 12 years.
Q. Are you still treating her for her sling?
A. No, I'm not treating her for that. The reason I saw her specifically was because she also has kidney stones.
Q. Is it also the situation that some patients switch doctors after their initial implant procedures? Is that something that happens frequently in this?
MR. WALKER: Object to form.
A. It may. You know, I'm sure that happens for a lot of different reasons, moves or whatever. It may. I'm not aware of how many or how often it happens, but I

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know I see other -- you know, some other colleagues' patients later, for whatever reason, so I'm sure it happens.
Q. And that was my next question. Do you treat complications that arise with patients that were implanted by other doctors?
MR. WALKER: Object to form.
A. Well, here's how I would answer that really more specifically. The way that my practice is now is I'm kind of known within the community to help with more complicated incontinence issues, neurogenic type of bladder problems, incontinence of different types. So I see a wide variety of patients for all different reasons of incontinence. It may not necessarily be stress. It could be urge incontinence.
Unique to Knoxville, though, I will say is -- well, is that the gynecologists tend to not do any of the sling procedures. They end up sending them to the urologist. And so that's kind of a unique setup that we have here.
Q. So do you treat mesh-related complications in your practice today?
MR. WALKER: Object to form.
A. If a patient has had a sling placed and they feel like they are having some issues with their bowel

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or bladder or incontinence, whatever, then I'll see them, just like I would see any patient.

Q. Do you ever refer them to another doctor to treat their complications related to mesh products?

MR. WALKER: Object to form.

A. You're assuming I'm having a lot of complications here.

Q. I'm saying if someone comes into your office that was implanted by another doctor, would you refer them on or would you treat them?

A. That's a good question. I mean, complications arise for -- well, you know, problems with any surgery, whether it be incontinence surgery, whether it be Interstim, whatever.

If I'm getting to a point where I feel like we're not making progress, then I'm not going to beat my head against the wall and I'm going to try to get another set of eyes to then see this patient. So the bottom line is, if we're not making progress with the patient, I want the patient to get better. So whatever that takes to get better, you know, we'll make that happen. It doesn't happen very often. And in all honesty, I just don't see a lot of my patients back that are having problems after putting these in.

Q. Have you, on any occasion, treated a

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patient that you have implanted one of these sling devices in -- let me start that over.

It you can tell me, how many patients that you've implanted a sling in have come back to you with problems that you treated them for?

MR. WALKER: Object to form.

A. What kind of problems are you describing?

Q. Anything that potentially might be related or that they believe might be related to their sling.

A. Well, I've seen patients after -- can you rephrase your question?

Q. Sure.

A. I guess what I'm having a hard time with is you're implying that it's an issue with the mesh, and I really don't feel like it's the mesh itself that's the issue a lot of times. But every time you do surgery on a patient, whether it be with a sling or, like I said, Interstim, or any other reason that the patient may have some problems with their surgery, I see them back to help them get through their issues.

So as far as the mesh itself, I don't know if I can answer that, but I would say after, you know, pelvic surgery and it's something that they feel like is going on, I mean, I don't know, a handful of times.

Q. What type of complaints have you seen or

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treated with regards to your patients following their implant surgeries?

A. Well, I mean, after -- sometimes some of the incontinence returns. You know, of course, there's the rate of urge incontinence that occurs in some of these patients. I've had probably just a handful of patients who have had an extrusion. I'm trying to think of any others. I've had a few patients with a TVT-O that initially complained of some groin pain and then that eventually resolved.

Q. By "resolved," you're basing that on the fact that they didn't come back in for follow-up treatment?

A. No. No. Those patients, if they were having some discomfort initially, I made sure to get them back regularly. And I can honestly remember only just a handful of patients who had that, and made sure all of them resolved. So I can't remember only one case where I felt like there was a long-term problem.

Q. How many patients that were originally implanted by another physician have you seen and attempted to treat?

MR. WALKER: Object to form.

A. That's hard for me to -- I don't know. I would say -- I don't know that I can give you a specific number. Gosh, I don't know.

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Q. Is it greater than ten?

A. Yeah, it's probably around 10 to 15, somewhere around there.

Q. What type of complications, if you can recall, have you seen that have been --

A. Usually what I get --

MR. WALKER: You've got to let her finish the question.

THE WITNESS: I'm sorry.

MS. BAGGETT: It's hard for all of us to do because it's like we want to have a conversation.

BY MS. BAGGETT:

Q. So my question is how many -- or what types of complications have you seen in patients that were originally implanted by another doctor and treated them for?

MR. WALKER: Object to form.

A. Okay. So you're asking me how many -- what type of problems these patients have had?

Q. Yes, sir.

A. Okay. Well, like I was saying before, the majority of my practice is incontinence work. And so if another doctor has implanted them and they've had recurrence of their incontinence, that's usually what I'll

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see the referral for, and then trying to determine if it's a recurrence of the stress incontinence or if it's an issue with urge incontinence. So that's a lot of what I do.

Q. Have you ever treated anything more serious than just a recurrence that occurred with a patient that you did not implant?

MR. WALKER: Object to form.

A. Yes.

Q. What type of problems?

A. She had -- one patient, and I don't recall the -- I do not recall the actual device that was implanted, but I do remember one patient having a small extrusion.

Q. And do you keep track of all of the cases you do somewhere in your practice? The products that you implant, is there some system that you maintain that keeps track of the implant devices you implanted?

A. No, ma'am.

Q. So the same would be true for any conditions that you treat as a result of having had that implant implanted? You don't keep track of that either. That's what I'm trying to find out.

A. I'm not following your question. I'm sorry.

Q. Do you also track any of the adverse

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events that you may have treated?

A. Well, I'm not in an academic setting so I really don't have a need -- or it's not the need, but I don't have -- I'm not doing studies on my patients, so I don't have a registry.

Q. That was going to be my next question actually. Have you been involved with any studies or registries with regards to the sling?

A. No.

Q. Doctor, do you also implant POP devices?

A. No.

Q. Doctor, are you familiar with the difference between mechanically-cut versus laser-cut meshes?

A. I am.

Q. Tell me what your understanding is of the difference between those two devices.

A. Well, one is actually physically cut with some type of shears or some type of device, and the other one is cut on the side with a laser to give you the device shape. I don't know anything more than that, though, how they do it.

Q. And have you implanted both types of mesh?

A. I assume I have. I know I have. I know I have because TVT-Secur is laser cut and the TVT-O is, for

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the most part, mechanically cut.

Q. Do you recognize any differences between the meshes, the two types of meshes, when you look at them or feel them?

A. I don't notice any differences when I feel them. The only difference you can see is when the laser has come across the edge, there may be more of a heat-sealed type of look on the side of it. But there's no -- other than that, they feel the same, they look the same, yeah. It's not something in residency or in training that has been brought up. But, yeah, I know now.

Q. Are you familiar with the differences in the type of adverse reactions that are associated between the two types of devices?

MR. WALKER: Object to form.

A. No. Honestly, I haven't seen anything like that in the literature. It appears to me that the adverse events are about the same.

Q. Have you ever witnessed in your practice with the meshes that you have implanted that were mechanically cut -- have you ever witnessed any particle loss on those products before you implanted them?

A. Not that I'm aware of.

Q. Were you aware that the mechanically-cut meshes could lose particles or fray?

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A. I'm aware of that.

MR. WALKER: Object to form.

Q. And did that have any bearing on the types of products that you continued to use or chose to use?

A. No. What I would say to that is, you know, I base my decisions on the literature and outcomes and adverse events, and there's really nothing that would suggest that particle loss is an issue.

Q. Do you know if the particle loss has been studied in any of the literature that you have reviewed?

A. I'm not aware of any literature looking at specifically the particle loss in the patients.

Q. Have you done any research to see if there have been any studies regarding particle loss in the mesh that's used?

A. I haven't done a PubMed research for particle loss for slings, but I've read thousands of articles, and not one has ever discussed particle loss. So that in itself is a new concept.

Q. Have you also in preparing for your deposition today had the opportunity to review any Ethicon internal documents?

A. I have.

Q. Have you read any documents through that review that discuss particle loss in any way?

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A. Yes.
Q. What types of information was contained in the documents that you reviewed with regard to particle loss?
A. The only article -- or the only documents I remember seeing was based on internal documents in Ethicon; communications from one engineer to the next, or I don't know. I can't keep their titles straight, but I don't know if it was marketing, advertising. I know there was an engineer involved.
Q. Do you know whether or not there were any discussions in the documents that you read with regard to performing a study on the effect of this particle loss in the patients?
A. I don't recall that.
Q. Do you know if the documents that you read suggested that there may be a need to study this phenomenon in order to protect the safety of the patients that were implanted with the device?
MR. WALKER: Object to form.
A. I'm sorry. Repeat that.
MS. BAGGETT: Can you read that back?
(Thereupon the question was read back by the court reporter.)
THE WITNESS: That question is supposing

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that there's a problem with particle loss causing safety, and I disagree with that. But to answer the other part of your question is I think there were some general discussions about it, but I don't recall specifically trying to get a study involved, and I don't know that there's really a good need to have a study involved for that.
Clinically, there's really no -- you know, clinically, this idea about particle loss is a moot point. There's no -- prolene mesh is inert, for the most part. And any little suture bits that have been cut in the past, you know, those happen to have -- those happen all the time. When you cut the suture, you're going to have some particle loss. And those particle losses have never been documented or shown in any studies to be of any consequence clinically.
BY MS. BAGGETT:
Q. And you had mentioned just in your response something about polypropylene being inert. What do you base that on?
A. Well, reviewing some of the records, I do recall some conversations back and forth about the properties of the mesh, and one of them -- well, that was tossed back and forth in some of these documents, but more

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specifically, in the guidelines from the different professional societies, there's -- I believe there's discussion about being an inert mesh.
Q. Did you also review internal Ethicon documents that discussed the fact that the prolene mesh does suffer some form of degradation and may not be inert?
MR. WALKER: Object to form.
A. What I saw and what I remember reading -- and, again, I don't have the specific name and information, but what I remember is that there was some controversy about that and it was felt to be -- the comment that you just made was then subsequently found to be not accurate.
Q. I'm not going to mark this because I didn't bring copies, but I'm going to show you a document and you can look at it as well. It's a document labeled ETH.MESH 12831407. And this is a document that was provided to us by Ethicon in discovery of this case with regards to prolene explant study meeting minutes that took place October 8 of 1987. If you want to read over that for a second.
A. 1987?
Q. Yes.
MR. WALKER: Let me know when you're ready for the question.
MS. BAGGETT: And if you'll let me see it

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when you're done. I'm not going to ask you to remember anything you read on it, but just in general ask you some questions when you're done.
THE WITNESS: Here you go.
BY MS. BAGGETT:
Q. And after reviewing that document, would it appear to you that Ethicon was aware, at least as early as 1987, of the potential for their prolene sutures material to degrade?
MR. WALKER: Object to form.
A. The way I'll answer that is prolene has been around for 50 years, has been used in multiple different settings, transplant surgery, cardiovascular surgery, and it continues to be used. It's still on the market. And so whether there's some findings of changes in the mesh or not or on the prolene suture or not, you know, clinically, it really has no -- there's really nothing that I can -- from a clinical standpoint, there's no adverse events that we've been able to determine.
Q. When you were being trained on devices manufactured by Ethicon, you understood that those devices all contained the same type of polypropylene; the TVT, the TVT obturator and TVT-S devices all contained the same type of mesh, which was the prolene mesh, correct?
A. Yes.

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Q. And you knew that those were made from the same material that the sutures were made from. Is that accurate?
A. Yes.
Q. And were you aware back at that time of the potential for the sutures to become degraded?
MR. WALKER: Object to form.
A. I disagree with that. I would have to think that something that would be used as a suture for vessels would have to be proven to be non-degradable. And so based on that and the fact that I've seen the mesh after it's been removed and there's no visible change in the mesh, I really can't agree with the initial premise of your question.
Q. I think my question was just simply did you know that the polypropylene had a tendency to degrade after implantation back when you were being trained on the devices.
MR. WALKER: Object to form.
A. Well, are you basing it on that one article?
Q. Well, I'm just asking --
A. Because from a clinical standpoint, we would assume all surgeons are trained to look at prolene suture as a non-degradable suture. So that is the premise

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that I came into this with and continue to use, not that -- well, I'll just stop with that.
Q. When was the first time you had heard of the potential of degradation with regard to polypropylene?
A. Not until late last year.
Q. When you began preparing for your report?
A. Yes, ma'am.
Q. I'm going to show you a document that's marked ETH.MESH.00004755, and I'll represent to you that this was another document that was produced in the discovery of this case. And this document is also dated in 1988, and it just has some notes with regard to some explants, and I just want you to look at it and then I'll briefly ask you a question.
A. Okay. You can ask me.
Q. Sure. What does this appear to be to you?
A. These are -- these are explants of something and it describes whether there's cracking or not cracking. I don't -- these are explanted something or other. I don't know exactly what these are.
Do you know what those are?
Q. Well, I don't want to misrepresent anything on the record, but my understanding was polypropylene material that had been explanted.
The next document I'm going to hand you is

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ETH.MESH.05447475, and this is an e-mail discussion with regards to, "Subject Line: How inert is polypropylene?" And take a second to...
MR. WALKER: You don't want to mark these as exhibits?
MS. BAGGETT: No, only because I didn't bring enough. I intended to get them copied, but I didn't. I ran out of time.
If I can see that back when you're done. Thank you.
BY MS. BAGGETT:
Q. And this document, as I said, was dated in 2007, so would you agree that at least as of 2007, Ethicon was still discussing the fact that there were changes in the surface of the mesh fibers and a question of -- that had been raised with regards to the inertness of the polypropylene?
MR. WALKER: Object to form.
A. I don't see anything in there about inertness. I think they are talking about tensile strength and ways to help prevent suture breakage.
Q. I'm going to hand you one more document on this subject. It's ETH.MESH.05447481, and it's dated July 6, 2007. It's also an e-mail chain.
A. Okay.

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Q. And my question is, continuing into 2007, they were still discussing the degradation of the polypropylene, and at this point they are actually discussing a new polymer that they may consider in future applications that doesn't have that same propensity. Did you read --
A. Can I see that one more time?
Q. Sure.
A. Thank you.
MR. WALKER: Object to form.
Q. Could you just tell me what the product is they are referencing in this document that you're reading?
A. Which product are you talking about?
Q. Well, I mean --
A. The new product or the older product?
Q. The new product that they are referencing potential --
A. They're describing something called a Pronova suture.
Q. By reading the document, does it sound like it suffers from the same potential to degrade as the original prolene suture?
MR. WALKER: Object to form.
A. Ma'am, I can't say much about it other than this e-mail, the way this e-mail describes it.

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There's no data on it. It's just a discussion between two colleagues.
Q. But in the discussion that you read, does it discuss the characteristics of this new product and do they different from the prolene suture?
MR. WALKER: Object to form.
A. Yes.
Q. You also mentioned earlier that some of the information where you learned about the inert qualities of polypropylene were through some of the societies that are involved in treatment of stress urinary incontinence and other urological disorders.
Is that what I understood you to say?
A. Well, yeah. I mean, I guess my point of saying that is that a large group to -- a large group of physicians to get together and discuss things and to come out with a consensus statement would have to include all these factors. And if they felt that a product wasn't safe or reliable -- and inertness being part of that, I suppose, although from a clinical standpoint, it's really not something we consider and it really has not been shown in any studies to show any value. But if those large group societies endorse the product, us as physicians would have to use that as our beacon to know that that's a safe and effective product that's endorsed by many physicians at the

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academic level that look at all these things.
Q. So is it fair to say that you as a physician rely heavily on the information provided to you through these societies?
A. I think that it's, you know, part of our decision-making process, and it certainly helps when one of these large groups is either advocating or in some situations they may not advocate a certain way of doing things. And to listen to that I think is part of our duty as urologists, to listen to the American Urological Association guidelines.
Q. Are you aware of the fact that some of the members of these societies are also employees of the device manufacturers?
MR. WALKER: Object to form.
A. I have no way of knowing that, ma'am.
Q. Would that --
A. Does it surprise -- I'm sorry. I interrupted you.
Q. No, I didn't let you finish. Go ahead.
A. I would assume that these physicians are probably consultants of many, many different companies. And so it wouldn't surprise me at all if they were consultants for Johnson & Johnson or Ethicon.
Q. Would that have any bearing on your

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reliance on the materials or the information that you are provided from these societies?
A. No. No, because for every physician that may be -- you know, there's a counterbalance there and these are not made by -- these guidelines aren't made by one individual. They're made by a group. And so it's a consensus statement. It's not an individual statement.
Q. Would you agree that if a device manufacturer were to try to affect the information that was being presented through these societies in some way that was misleading, that that would be unethical?
MR. WALKER: Object to form.
A. Can you break down that question, because it seems like there's two parts to it?
Q. Sure. Would you agree that it would be unethical for a company, a device manufacturing company, to use their influence with a society to misrepresent information about their product to the medical community and the public at large?
MR. WALKER: Object to form.
A. Ma'am, that seems to me a little bit insulting to physicians to think that we would let a device company make decisions for us. And I'm not trying to be ugly about it, but to me that would -- you know, as a physician, you know, we're not beholden to any company.

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And so, honestly, that's not part of my thought process. So I can't really answer that question the way you have it stated.
Q. I want to show you what's marked as ETH.MESH.10216874, and this is an e-mail chain dated August 2000, and it's with regards -- the subject line is AUGS Lecture/Content of Discussion, and I want to ask if you would just look at this for a second.
A. Okay.
Q. After reviewing this document, Doctor, does it appear that, at least based on what you read in this memo, that Ethicon has had conversations or meetings that were centered around having doctors represent -- let me start that over. That's getting too long.
What was your impression from reading this memo?
A. I need to look at one more thing before I can answer that question.
What's my impression from reading that memo?
Q. Yes, sir.
A. It sounds like a typical marketing person and any company trying to be encouraging of their product.
Q. Do you agreed that in marketing that a company is ethically bound to present truthful and complete

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information when they are discussing the products that they are selling?
MR. WALKER: Object to form.
BY MS. BAGGETT:
Q. Let me put it this way. Have you ever heard of a term called "fair and balanced"?
A. Yes.
Q. And do you agree that information that is provided by a company with regards to the products that they sell should contain fair and balanced information on both the risks and the benefits of that product?
MR. WALKER: Object to form.
A. To some extent. I mean, I wouldn't expect -- let me give you an example. I wouldn't expect a marketing person or a salesman for a company that sells me -- or wants to provide samples for, let's just say an overactive bladder drug, to give me all the benefits of their competitor, right? So from a physician standpoint, I know where this is coming from, I know everybody's -- but in reality what happens is I take that information and then I compile it with all the other information that's out there to come to our decision.
So does it surprise me? No, not really. That's their job as a marketing person. But does it influence the physicians? Not me. It shouldn't. I mean,

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we're not relying on their information to make decisions. We're relying on the clinical data that's out there.
Q. And do you -- with every study that you come across in your field, your area of expertise, do you not only read the study, but do you try to look at the underlying data that's involved with that study to determine whether or not you feel it's an adequate study?
MR. WALKER: Object to form.
A. Are you asking me if I always do?
Q. Yes, sir.
A. I try to. I don't know that I always do. But it's part of the whole -- you know, as a physician, that's part of the whole process. I mean, we don't live in a vacuum. So the research that we did in residency, all the studies that we did beforehand, all the books that we read, I mean all that stuff gets assimilated and then this is part of that assimilation, right?
MR. WALKER: Renee, when you hit a stopping point, could we take five minutes?
MS. BAGGETT: Sure. Let's go ahead and do that now.
(Thereupon a break was taken 9:33 a.m. to 9:37 a.m.)
BY MS. BAGGETT:
Q. Doctor, before we took a break, we were

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talking about societies, such as AUGS. And what are some other societies that you're familiar with with regards to this field of practice?
A. Well, American Urologic Association, Society for Urodynamics in Female -- I don't remember the acronym. SUFU or -- let me look through here. There's one for the American -- what is it -- Urogynecologists Society. I'm not very good with acronyms. I'm sorry.
Q. Me neither. That's all right. That's plenty.
SUFU is one you mentioned, and are you familiar with the position statement that was jointly put out between AUGS and SUFU?
A. I remember reading it, but can you give me a second to review it?
Q. Well, if you want to, in a second you can. I want to show you some different documents, and this may remind you what it's about. But if you need to, you can certainly take time before you answer any questions.
I'm going to hand you what's been marked as MIL00282, and this is an AUGS/SUFU MUS task force agenda. And this, I'll represent to you, was provided to us in the production of documents obtained in this litigation. You don't have to necessarily focus on the highlighting. That was for me.

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A. Okay.
Q. And I'm going to hand you now what was marked as MIL00268.
MR. WALKER: Rebecca, this is a seven-page document?
MS. BAGGETT: Yes, I believe it is.
BY MS. BAGGETT:
Q. Did you have a chance to look at it the way --
A. Well, I mean, I can sit here and spend some time reading these things, if you want me to.
Q. That's not my purpose. I wanted --
A. Was I --
MR. WALKER: Just wait for the question.
Q. Do you have an opinion of -- or do you understand what the documents were that I gave to you?
A. I didn't have time enough to look at the second document.
Q. That's fine.
A. The first document was some meeting agenda notes.
Q. And it was with regards to the position statement?
A. Yes.
Q. And the second document I handed you --

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and I'll let you look at it again if you want to -- it appears to be a draft of that position statement with some comments in the margin with regards to editing notes. Would you agree with that?

MR. WALKER: Object to form.

A. I agree. Did I have this beforehand?

Q. I doubt it. And I'm not going to ask you about the content. But as least as far as the two documents that I just handed you, does it appear that there was some input by Ethicon with regards to the drafting of that position statement?

MR. WALKER: Object to form.

A. Ma'am, I can't make heads or tails of this in the short amount of time that you've given this to me, so I really can't comment.

Q. Sure. But as far as what this appears to be on its surface, what does this appear to you to be?

A. I don't know, because I don't know who wrote this. I don't know who's making the comments. I mean, I don't -- I haven't had enough time to really dig my teeth into it.

Q. That's all right. I'm not going to ask you to criticize it. My question then, based on your review of these materials, would it bother you to know that a device manufacturer was having input over the position

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statements or the guidelines that were being circulated to physicians in the community about the devices that they were selling?

MR. WALKER: Object to form.

A. No, it would not bother me, and I'll explain why. Because when a physician is doing a procedure with a certain device and that device is getting good results and they feel like it's an adequate treatment, for them to feel like there's an issue with it. A lot of times there just needs to be more information. There needs to be support from the other physicians who you trained with, who your colleagues are. So there needs to be some rallying point.

Irregardless, just like I mentioned before, it still comes down to the body of work in the medical literature to come up with those guidelines, though. It doesn't bother me at all.

Q. Would it bother you to learn that any information that was being shared with the medical community through these position statements, that the information being shared was being misrepresented or withheld, or if there was important information being withheld?

MR. WALKER: Object to form.

A. I feel like I'm not quite catching your

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drift there. Can you explain that again?

Q. Sure. I'm going to hand you what's been marked as ETH.MESH.06828907, and it's another e-mail chain.

A. Okay.

Q. And in this document that I passed to you, that's an e-mail chain discussion between internal employees at Ethicon with regards to a safety aspect of -- I lost where the device is that was being discussed. At least with regards to this information, it's discussing one of the adverse events that Ethicon learned of, and the discussion was to not include that information in this submission and spin the safety aspect rather than talk about the complications. Is that your --

A. Do you mind me looking at it?

Q. Sure.

MR. WALKER: Object to form.

A. Well, I don't know if this is related to a sling or which sling or if it's related to pelvic organ prolapse. I don't have an idea. So it's really incomplete. So because of that, I don't really have a whole lot of way to answer it, although I will say that internal communications between Ethicon are just that, and still don't -- you can't hide -- you know, their conversations between each other are their own conversations. That has no bearing on the data that's out

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there that's been reported by thousands and thousands of papers. So I think their getting upset about something is their just own worry. It's not necessarily something that's of any clinical concern.

Q. Are you familiar with the MAUDE database within the FDA and the requirement of device manufacturers and other even pharmaceutical manufacturers to report adverse events that they learn of through their work?

MR. WALKER: Object to form.

A. I know something about the MAUDE database. I really don't know all the details about the MAUDE database.

Q. But you're at least familiar with the fact that doctors are required to report adverse events that they experience with the products that they use?

A. I don't know that "required" is the right word. I don't know that for a fact. But is that suggesting that any type of complication that I'm having I'm supposed to report back to the MAUDE database?

Q. Well, I'm asking you, are you familiar with the concept that doctors, when they see an adverse event, have an obligation to either report it to the FDA or back to the manufacturer? Are you familiar with that at all? Is that your understanding?

A. I'm not familiar with that.

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Q. Are you aware of any studies that are based off of the adverse events that are reported, either or both to the MAUDE database or to the manufacturers? Are you aware of any studies that use that data as part of their study?

A. Not specifically. It wouldn't surprise me if there is, but I don't know off the top of my head.

Q. Are you aware of any requirement of the manufacturer to provide the FDA with adverse event information that they obtained from the doctors in the field that are using their products?

A. I don't know that I am or not. The reason I'm hesitating a little bit is because, as I stated before, I do proctor Interstim cases, which is an implantable device. And so if there's a problem with a device, then I get some paperwork that I'm supposed to fill out. But I don't get anything for anything else. I don't know of any other database or studies or -- I don't remember your exact question, but I don't know that I'm real familiar with that.

Q. Okay. If a manufacturer, a device manufacturer, is aware of complications that they are seeing in the medical community, do you feel that they have an ethical responsibility to advise the doctors using their products of the rate of incidence that they are seeing

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these problems?

MR. WALKER: Object to form.

A. Well, I suppose, but let me -- to me, that doesn't quite make sense, because I don't know how the device manufacturers are knowing how the patients are doing when they are not the one seeing the patients. So I would think that more likely that the physicians themselves who are conducting the studies would actually provide that information in all the 2,000 or 3,000 different studies that have been done.

So I don't know that the manufacturer has -- I mean, I think that gets out to the manufacturer secondarily through the physicians, but I don't know that they are the ones that are seeing it. So I think it's already out there of anything going on with any products because they can see that.

Q. In the cases where the doctors are not involved in studies and not gathering data for a particular purpose, simply doctors who have experienced an adverse event with their patients that they bring to the attention of the manufacturer, do you feel that once the manufacturer learns this from the doctor that's in the trenches, not doing the study, that they have an obligation to report that information and to investigate it to make sure that it's not a red flag of some sort of problem with the

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device?

MR. WALKER: Object to form.

A. That was a long question. But the answer is, no, I don't think they have to report every adverse event.

Q. Let's go to your report. We're doing two separate today, so we're going to be talking about TVT-O and TVT-S. Do you care if I go with one first or the other, because my outline kind of goes by the report.

So are you here today to offer any opinions with regard to the TVT device, the retropubic device?

A. No, ma'am.

Q. Because I noticed in your report that you do have sections with regards to the TVT device.

A. Yes, ma'am, and that's as a baseline because that's where it all started. So to come up to date with things I needed to be as complete as I could, and that had to be part of my report in order to get to where I wanted to get.

MR. WALKER: Yeah, we're only disclosing him as an expert for TVT-O and TVT-Secur.

Q. Okay. Well, then I won't drill you too hard with the TVT device today other than just the general that needs to be included to understand the materials we're

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going to be going over.

The first section I want to talk to you about is you've got a section entitled "Stress Urinary Incontinence," and it's on page 2 of your report.

A. Yes, ma'am.

Q. And you discuss urinary incontinence and a little bit of the background on it, and I just wanted to focus your attention on the last paragraph where it talks about the economic burden. The very last sentence, "The economic burden of SUI is in the billions."

Do you recall where that number came from?

A. No, actually, I don't, but I do remember that was part of one of the things I read, but I couldn't -- well, after I read it I remember thinking about it, and it's been in my head a long period of time. It wasn't necessarily associated with coming up with this report specifically, but, you know, because of all the work that I do in incontinence, it's something that I came across in the past and it just stuck with me.

Q. Have you also reviewed anything that discusses the economic burden of treating complications with regards to sling devices?

MR. WALKER: Object to form.

A. Have I reviewed that?

Q. Yes, sir.

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A. I tried, but there's a lot overlap between stress incontinence. Some patients have stress incontinence, some patients have urge incontinence, some have both. So to really pinpoint it for stress incontinence is very, very difficult.
Q. Are you familiar with the -- or are you aware of whether or not Medicare had to come up with a coding system to treat complications with regards to medical sling devices?
MR. WALKER: Object to form.
A. Was I aware that Medicare came up with a coding system?
Q. For billing for services performed to treat complications with mesh devices.
A. Oh, you mean a different CPT code?
Q. Yes.
A. Yes, I think I was aware of that.
Q. And in your research, you did not come across anything with regards to Medicare or Medicaid that suggested what the economic burden has been with regard to the treatment of the adverse events relating to the mesh device?
MR. WALKER: Object to form.
A. Again, going through all this, I tried to find as much information as possible, good and bad, and I

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couldn't find anything specific for that one particular question that you had.
Q. So you don't know the economic burden with regards to the treatment of complications related to mesh devices sitting here today?
MR. WALKER: Object to form.
A. No, not specifically.
Q. On page 3 you talk about the risk factors for developing SUI, and some of them are -- include age, Caucasian or Hispanic race, obesity, smoking, chronic cough, pregnancy and childbirth, nerve injuries to the lower back and pelvic surgery. Those were ones that you listed, at least here.
Are you aware of whether or not those conditions are also contraindications to having the procedure or a sling device or a transvaginal mesh device implanted?
A. You're asking if any of these things listed are a contraindication to having a sling placed?
Q. Yes, sir.
A. Yes.
Q. Which ones?
A. Pregnancy.
Q. Anything else?
A. Not that I'm aware of.

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Q. And in your practice, based on your experience, should any of these conditions be contraindications -- other than pregnancy and childbirth, should any of these other conditions be contraindications for having a transvaginal mesh device implanted?
A. Well, each individual that comes in my office has their own set of problems. They're unique, right? So you have to take all these things into consideration to determine if that's the best way of going about things.
I mean, a little lady who is 90 years old who may leak a little bit here and there and wears a pad is maybe completely fine with that. And another one who's 90 may come in and be completely upset about that. So, you know, you have to factor all that into consideration, their health. And so are these general contraindications? Other than pregnancy, those are all things you have to factor, but they are not contraindications.
Q. But they are things that each doctor should consider when deciding and having a conversation with the patient about whether or not to have the device implanted. Is that fair?
MR. WALKER: Object to form.
A. Rephrase your question again.
Q. Sure. But this is a conversation that you

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would have individually with your patients in discussing the risks and benefits of having the device implanted. Is that fair?
A. Well, what this list is, is why do people develop urinary incontinence in the first place, right? Not necessarily would that prevent them from having the surgery afterwards. I mean, if they are obese, would you like the patient to lose weight? Yes. But in all likelihood, is that patient likely going to lose a lot of the weight? Probably not significantly in a short period of time.
So, again, these are things you discuss with the patient before and you tell them, you know, you're at risk for the incontinence because of this and you're also at risk for this recurring possibly afterwards because of these things if you don't change your habits, quit smoking, et cetera. So those are conversations you have to have with the patients.
Q. I guess that's what I was getting at. If these are risk factors for the condition of being incontinent in the first place, these risk factors also increase the risk that a patient may develop a recurrence, and does that in any way factor into your recommendation on whether or not to use the device?
A. So, no, it does not, and I'll tell you

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why. It's because these patients are coming in because they are upset, they are depressed, they are sad. They are having to spend a fortune on pads and they're upset. And so if you say, well, ma'am, you know, you are slightly obese, so, therefore, no surgery, well, that patient is going to keep -- I mean, is going to be upset about all these other things. So they're obese because they can't work out, right? So maybe if you place a sling, now they are able to work out and lose weight.

So I guess the answer is it's more convoluted than that. It's more complicated than just saying those are risk factors for recurrence. I mean, yes, but the alternative is maybe nothing and they would be very unhappy with that, and a hundred percent recurrence rate if you never do surgery in the first place.

Q. But as far as the risks that are associated with the procedure, when you're balancing the risks with benefits, if there's a high likelihood of recurrence, is it, in every situation, worth the risk that they are exposed to these other potential adverse events in order for the product not to work?

MR. WALKER: Object to form.

A. Well, in my hands and in the studies I've seen, adverse events are low enough that it's reasonable, and you have that conversation with the patient

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individually so they understand the risks and the benefits and then they can make their own informed consent, just like any surgery, all right? If they feel like the risks are too high, then they may opt not to have surgery.

Q. If you look down at the paragraph right before treatment options for SUI, you discuss some questionnaires that could be helpful, and you include the King's Health Questionnaire, Bristol Female Lower Urinary Tract Symptoms Questionnaire, Stress and Urge Incontinence Quality of Life Questionnaire.

Do you know when these questionnaires began being used in your field?

A. I don't know.

Q. Have they been around for a long time?

A. I'd have to go look and see. I'm not exactly sure when they came out.

Q. Have you reviewed each one of these questionnaires before?

A. It's been a while since I've looked at them.

Q. Do you have any idea who drafted those questionnaires?

A. I don't.

Q. Do these questionnaires cover all potential problems that these women may experience with

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regards to the treatment that they are receiving?

MR. WALKER: Object to form.

A. No. Those are just part of our -- you know, when they are coming in to talk to us, they're just part of the whole process. It gets us started on our conversation, but there's no way that we use those questionnaires solely to make our decision on. It's part of the conversation that gets us going and going through all the questions that we need to ask to determine if they are a candidate or not.

Q. And you wouldn't rely on these questionnaires, for example, if they are filled out after they've had the sling procedure to give you a complete picture of what the patient may or may not be experiencing with regards to their mesh device. Would you agree with that?

MR. WALKER: Object to form.

A. It can be used at any point in time. I don't know that it's all that helpful. I mean, again, it gets the conversation going and so patients feel more comfortable talking about some of the things that maybe they hadn't thought about.

Q. Are these the same type of questionnaires that are used in some of the studies that you've reviewed regarding this litigation?

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A. These questionnaires are -- no. Well, let me rephrase that. They could be, but it's not something that I hunted down to find. And they may be part of the questions, but when we're looking at the data, it doesn't say the King's Health Questionnaire number was X, Y or Z. You know, you're looking at preoperative stress incontinence with the urodynamic studies look like this type of thing.

So could they be? They could be, but they are not specific and, you know, they are not a very important part of what we're -- how we discuss things with the patients.

Q. In these studies that do include some form of questionnaire in determining the data and the opinions that come from those studies, is it important if you're trying to determine safety and efficacy for a questionnaire to be complete on at least the things that are being studied?

MR. WALKER: Object to form.

BY MS. BAGGETT:

Q. For example, if this study were geared towards determining how many patients had experienced dyspareunia with regard to a product and you would expect that that questionnaire would have a question with regards to dyspareunia. Is that fair?

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A. If there's a study specifically looking for dyspareunia? Well, first of all, I don't know how you would make a study looking just for dyspareunia, right? But if you're looking just for all patients, they can be helpful, but these don't necessarily mean that that's the only thing the patients -- I don't think your question -- I don't think what you're saying and what I'm thinking is jibing, because I'm thinking of these questionnaires as just basic forms the patients fill out when they come into the office to help with the clinician determining if the patient is a candidate for surgery.

I think what you may be referring to is some type of useful tool that's used in studies to help determine quality of life and adverse events. And, honestly, I don't view them the same way that you're viewing them.

Q. And I think maybe that transition is what I need your help understanding. It may not be this exact questionnaire, but would you agree that for the studies that include a component where the only information that they obtain from the plaintiff is through the questionnaire, do you believe that that questionnaire should include some questions with regard to the adverse events that you are trying to study with that particular study? And by that I mean if -- I understand you said that

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you wouldn't have a study just based on dyspareunia, but if that was one of the things the study was supposed to report, would you expect that the questionnaire should have a question -- series of questions with regards to dyspareunia in order to be able to report in that study whether or not dyspareunia and the frequency and the severity, things like that? You would expect that question to be asked in the questionnaire, would you not?

MR. WALKER: Object to form.

A. Yeah, that's a good question. I think that it's interesting. You know, when I was going through this, I was looking specifically for dyspareunia rates in the early stages of any type of stress incontinence surgery, and they're just not there. They don't mention them, all right? There's a few studies that do. But if you're asking me specifically for adverse events, I think each study individually is set up specifically to figure out what outcomes they want. And so it could include dyspareunia, it could not. But it really depends on an individual study, the way it's set up, you know.

Q. And so I guess the purpose of the study somewhat drives the information that will be contained in that study. Is that what you're trying to say?

A. You said "study" twice. I'm not quite sure I understand how you --

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Q. So the purpose of the study, whatever the purpose is, is what the study will ultimately report on. Is that fair?

A. Not necessarily. You might find things you weren't expecting to find, or you might find things that you'd have to stop the study for them. I think in general people try to set studies up initially to be able to predict the future of what they are going to find, but they may find things that they weren't expecting. I think that's what happened in the early years before they were really looking at this. They weren't expecting to find any issues. Before mesh was even on the market, you know, they were looking at these studies, and they were very specific about retention rates and those things. But they were finding these other things and then that kind of propagated from there.

Yes, maybe, but not necessarily every time.

Q. Page 4 of your report, if we could look down. And I know I'm not going through it line-by-line. I'm trying to hit some of the more significant points to me so that I understand what's been proposed here and what your opinions will actually be.

I guess this would be a good point for me to ask you, are all the opinions that you hold in this case

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contained in your report?

MR. WALKER: In terms of his general opinions?

MS. BAGGETT: Yes.

THE WITNESS: Are all my opinions in this report? As of now. Those opinions may change.

BY MS. BAGGETT:

Q. And that would be based on what?

A. Data.

Q. Since the date that you finalized this report, has any additional data been reviewed by you that affected your opinions in this report?

A. I've reviewed other data, but nothing that's affected my opinion. Again, you got to remember, I mean, part of my daily routine is reading, you know. And so reading about this, reading about other things I do, so I'll continue to monitor it.

Q. I'm trying to understand this section under midurethral slings in that second paragraph.

MR. WALKER: On page 4?

MS. BAGGETT: Yes.

BY MS. BAGGETT:

Q. "One constant factor over the years since the first procedure, there has never been one procedure that has high success rates with good durability and with

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low complication rates until now with the midurethral slings. If there had been, then there would not be a host of operations that have been tried and failed over the last hundred years."

Is there any study in particular that you base this paragraph off of?

A. Not one in particular. I think the point of that is there's been thousands of studies done, and initially the studies were done to compare midurethral slings with either what was the standard at the time, either Burch or pubovaginal slings, right? So at that point, it was fairly obvious there was a lot less problems with the midurethral slings than there were with the Burch and the pubovaginal slings.

So that transitioned into the studies now being all done comparing to each other. It's rare you find studies comparing to the pubovaginal slings or the Burch procedures. And so in the past, that's never been the case. So now you're seeing a transition of all the data to just look at those different corporations that make the different products. And the other things are still available, but rarely used.

And so that's what my comment on this is, is that you're seeing a transition from, hey, we need to try this, we need to try doing a bone anchor, we need to

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try using cadaveric fascia, we need to try using autologous fascia, we need to try incorporating some type of mesh in our own way, we need to go make an incision laparoscopically. All these things were done until these mesh slings came around, which changed the complete complexion of everything. If they didn't work, weren't successful, then we would have lost that. We would continue to be searching for something that was better.

Q. That's the point I was trying to get at, is searching for something better, that component of it.

Is it not true these device manufacturers continuously try to improve on their products and develop a better mesh?

A. I hope so.

Q. So that's one of the reasons why -- or what do you understand one of the reasons for the single incision sling being?

A. So what I mean by "I hope so," is that if a company stands pat with the product that is has and never tries to improve upon it, then that stalls innovation. We would never get to point we're at, right? So I'm hoping surgeons, physicians, clinicians, engineers, companies, are all trying to improve upon what we already have. So, yes, I would expect that.

Did that answer your question adequately?

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Q. For the most part I think. I think we'll get into it as we get later into it. If not, I'll come back to it.

Now, you were discussing some of the earlier procedures, such as the Burch and the autologous slings. Are you aware of any more current studies that compare those procedures with mesh products or not and what the data -- if the data has changed with regards to the cure rates of each device? Or each procedure, sorry.

A. I can't remember if the Shim study looks at all the pubovaginal slings and Burches.

How recent are you talking?

Q. I guess, to be more precise, are you aware of any changes in the medical literature with regard to the comparison between the prior procedures without mesh versus the procedures that use mesh?

MR. WALKER: Object to form.

A. I can't think of any.

Q. If you look on page 5, section Rationale on Clinical Decision Making Favoring TVT, the second-to-last paragraph it starts, "Making decisions based on the medical literature is what allows us to make informed rational decisions." And I think you alluded to that earlier in some of your responses, that you're the type of doctor that reads the medical literature and learns

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from that.

Is that a fair representation of what you said earlier?

A. Yeah, that's adequate.

Q. Then it goes on to say, "How do we make those decisions? Partly on personal experience, but significantly on the experience of others relayed in medical journals. Hopefully and ideally this is unbiased, unflawed information, but deciphering information presented while understanding this bias is also a learned skill."

What did you mean by that?

A. So part of what happens is we get bombarded with this study, this study, this study, this study. And after you're reading numerous studies, you start to see this is a good study, the way it was put together, it was well put together, this study is flawed for these reasons, there may be a bias because this surgeon only likes this type of procedure. So those are all built in.

Every study is going to have a little bit of a bias. So you have to be able to look at that study in the back of your mind thinking that this physician or this group of physicians is looking at this specifically. What can I see in that study that would unbias it and then be able to look at it more objectively.

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Q. Would one bias, in your opinion, be based on whether or not the investigators are involved with or have support from device manufacturers?
A. That's part of it, sure.
Q. And is it important in your role as a treater of women with incontinence using these devices -- is it important to you that the information in these studies is as unbiased and unflawed as possible?
MR. WALKER: Object to form.
A. That's an ideal situation, right? Rarely do we come up with that. That's part of reading the journals, is to say where does this person's background come from and then interpret it based on that.
Q. But as the doctor working in the trenches and using these devices, do you always have time to go back and look at the underlying data and research the investigators to determine the reliability of the study?
MR. WALKER: Object to form.
A. So there's those type of studies that are individual studies, you know, whether they're randomized controlled or whether they're just case studies or retrospective studies. So that's part of it. But, then, you know, that's a part of the puzzle, right? That one study is a small part of the puzzle. And big meta analysis, those are very helpful.

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So, yeah, I don't necessarily look up every individual. However, it's oftentimes disclosed right there on the front and so -- or the urology community is pretty small. The same physicians tend to write the same articles and so you kind to know already where a lot of those people are coming from.
Q. But do you agree that it's important that the data that is obtained from the investigators in these studies is presented accurately and truthfully?
MR. WALKER: Object to form.
A. Ideally you would, but every study -- you're going to be able to find a flaw with every study somehow, whether it be the way they present it, the different types of statistical analysis they are using to try to prove their point. Those are the things with years and years and years of reading these journals, you are able to see through a little bit.
Q. If the data in any particular study has been manipulated or reported inaccurately, with regards to, say, the adverse events that were seen in that particular study, and it's not obvious to you on the face of the document, then would you agree that you can't relay anything more than what is apparent in that study to the patients that you treat?
MR. WALKER: Object to form.

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A. I'm not exactly sure how to answer that question. But I think what I'm hearing from you is do I rely on one specific study to relay to my patients.
Q. Well, it's a little more than that. I'm just saying in all the materials that you reviewed in the course of your experience and your field of study and your treatment of these women, all of the materials that you review influence your understanding of a particular condition or treatment. Is that fair?
A. I think that's fair.
Q. So if any of that information was wrong in some significant way, the information that you relay to your patients when you're having this discussion with them about whether or not the treatment is appropriate for them, you cannot relay information that you don't have to a patient that would allow them to make the decision based on that information. Is that fair?
MR. WALKER: Object to form.
A. So when I get an individual study, if that individual study is leaving out information and it seems contrary to what's already been published, that's a big red flag, right? However, that should be ferreted out over time, and that one particular study may not be in a month from now or a year from now reproducible.
So any time I get an individual study,

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again, it gets put in the database, processed. But if I get something that's contrary to what's already been published, then that tells me I need to continue and pay attention to this to see if there's other studies to reproduce that one study.
That happened with, you know, testosterone usage back and forth. So now it's kind of swinging to one side. So now my antenna is up to think about how -- if there's going to be more studies on testosterone to support what's already out there.
The same thing with the slings. If there's something out there that catches my eye, there better be another study coming down the road that's going to either refute it or confirm it. And that is a continual process.
Q. But it's not always obvious on first glance whether or not a study has flawed data or has presented data in a flawed way?
A. I assume every study has a little bit of bias. So I'm always sceptical when I read any study. I don't think you can look at one study and say, oh, my goodness, this is a panacea of all studies, right? So is there going to be things that may be left out, either purposely or unpurposely? Possibly.
Q. Does that bother you in any way with your

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treatment of these women and recommending the product to them, that there is bias -- do you feel in any way that that affects your practice and your relationship with your clients in recommending a particular treatment?

A. No.

MR. WALKER: Object to form.

THE WITNESS: No. And, again, because of what I said before, it's just part of the equation.

BY MS. BAGGETT:

Q. Do you think it's fair to women receiving these products to receive them based on flawed information when that information was known and could have been provided before they were treated with the product?

MR. WALKER: Object to form.

A. Well, you said -- to answer that question assumes I'm saying it's flawed information.

Q. Okay. Let's do it as a hypothetical.

A. Okay.

Q. If you have a patient that you're treating with a product and the information that you've obtained in all your research suggests that it is the product that's appropriate for that particular patient, and you find out later that there was something about the data that was not presented to you that made it less appropriate for that

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person, which resulted in them sustaining some complications they could have avoided, would that bother you?

MR. WALKER: Object to the form.

A. That scenario wouldn't happen.

Q. Could you explain that?

A. Well, because if you're basing your decision making on one study of one product, then you shouldn't be performing that procedure. It's not until you've looked at, you know, thousands and thousands and thousands of these studies can you really come to a conclusion -- not thousands of study -- I should say thousands of patients being treated -- before you could really say -- you know, you may be able to hide one study, but you can't hide 500 studies. You can't hide a thousand studies. If there was a new product that was out that I wasn't familiar with and I had a study, I would wait until there was a little bit more data, me personally.

Q. Were you familiar -- we'll get back to that in a minute.

Do you agree with the concept that a device manufacturer should provide all information that they know about the adverse events that have been associated with their product before they put it on the market?

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MR. WALKER: Object to form.

A. No. There's no way to predict every -- I'll just leave it at that.

Q. Okay. Let's turn to page 6. In the second-to-last paragraph you say in your opinion, the treatment for stress urinary incontinence should be viewed in different eras before the TVT, which was cleared by the FDA in 1998. And then the next sentence I wondered if you would explain that to me. "The number of different types of pubovaginal slings, bone anchor slings, retropubic surgeries are numerous generally because of lack of long-term efficacy combined with the morbidity associated with each treatment." If you could explain that.

A. Sure. So I guess my sentencing wasn't very good there, or sentence structure. It's been awhile since I took English.

What I'm trying to get across is that -- like we mentioned before, before midurethral slings we would do these other types of surgeries. Well, there was always -- none of these surgeries were really device-driven. They were all individual. Maybe the bone anchor slings were somewhat device-driven. But by and large these were all just different types of surgeries using different types of material. They weren't very reproducible because there was no set way of -- you know,

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surgeries that you could look and see this is how you do the surgery. But each individual physician had their own way of doing that particular sling or bone anchor or retropubic or what have you. And it's hard to standardize, number one.

Number two is, over time you kept seeing that these procedures were -- just people were either having a high number of problem with retention with the pubovaginal slings, or over time these things were just wearing out and their incontinence was returning at a much higher rate than what we would see with the midurethral slings.

So efficacy, so lack of ability to fix the problem, and combined with the high rate of problems that they were having with them led to the situation now where we have a more effective, less morbid procedure than before.

Q. Okay. So if I understand you correctly, you're suggesting in this paragraph that the midurethral slings have better efficacy and less morbidity than things like the pubovaginal sling and other surgeries that do not include mesh. Is that fair?

A. That's fair.

Q. Okay. The next paragraph begins right after that and starts, "Also, as a physician and surgeon, I

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appreciate and utilize the current medical literature to shape and change my practice with the patient's best interest at heart. The literature is culled and reviewed to stay current with trends in medicine. Without that continued dialogue between practicing frontline urologists and academic urologists, there becomes a disconnect between what is theoretically going to possibly happen and what is happening with each individual patient."

The section next is what I really want to ask you about. "The device companies listen to the frontline high-volume urologists to let them know what they like and don't like about each of their products. This message is then relayed eventually to the academians who have the time and resources to do large volume, randomized clinical trials." I want you to explain that a little bit for me.

A. So, you know, it's like a pyramid. So the bottom of the pyramid is all the practicing urologists who see patients, do surgery, you know, take care of patients in the hospital, those type of things. A lot of volume, lot of patients, but no time to do any, you know, really data gathering to present articles.

So how does that -- all those patients, how do we-- because that's a huge number of patients compared to the number of patients that are in the studies.

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So how does the whole process occur? Well, at the meetings, just talking to your colleagues, you know, those type of things get disseminated through the sales reps. Things that, hey, I'm seeing this with this product, I'm seeing this with this product. We need to, you know, look at this. So that gets disseminated up the corporate chain of issues. And then also it goes up the academic chain with the urologists who are more at the top. They don't see as many patients so their volume is lower, but they do a lot of paper writing, right? And so people read the papers, right? We have no voice as working, practical urologists. So how's does our voice be heard? By making sure that the other urologists know what's going on.

Q. I guess that's what I was alluding to a little earlier in some of our discussions.

So based on the practicing doctors in the field, they're relaying information on what they like and what they don't like about the product, including potentially any adverse events that they've had, they're relaying that back to the company?

A. Uh-huh.

Q. And then the company is then relaying that to the academians. Is that what you're trying to say?

A. Not only that, back and forth between the clinicians and the company. There could be a dialogue

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there, depends on how open that is, but then also up to the academic guys, yeah.

Q. Are you suggesting with this section that when a manufacturer learns about something good or bad that they should share that information --

MR. WALKER: Object to form.

MS. BAGGETT: -- with the medical community?

THE WITNESS: I think that's something that each individual -- well, I think that's something that each individual company has to decide on their own. And then I think also that it's not necessarily something they have to share with the community, but it's something that needs to be evaluated and looked at and discussed.

I mean, look, there's no perfect procedure for anything and so it always can be improved upon. And that's my point, is if we just said, oh, this is perfect, we never have any issues with anything, then there's never this idea about improving upon what we already have.

BY MS. BAGGETT:

Q. Do you hold any opinions or are you familiar with the FDA review process for getting devices to the market?

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A. On the surface, but nothing in detail.

Q. You're not going to hold any opinions here today as to whether or not Ethicon complied with the FDA regulations for marketing their products?

A. I know they went through the proper channels to get the FDA to approve it. From a physician's standpoint, that's really all that I'm concerned about.

Q. What do you base that knowledge on?

A. I'm not sure I understand what you're asking me.

Q. Well, you said the fact that they were approved through the FDA.

A. Well, I guess I'll put it to you simply this way. As a clinician, if I know it's FDA approved, then I feel like that's an adequate way for each individual product to be cleared. And the amount of hurdles it has to go through to pass the FDA is substantial enough that that's their job, that's their role as a regulatory -- you know, I'm not a regulator so I don't know all the rules and regulations. But I do know once it comes to market that, you know, we should feel that the FDA has done their due diligence.

Q. And are you familiar with the difference between having a product cleared versus approved?

A. Yes.

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Q. And what is your understanding of that distinction?
A. One has to do with devices and one has to do with medications.
Q. Are you familiar with something called the (510)k process?
A. Through my review of things I have become familiar with it somewhat.
Q. What's your understanding of the difference between the 510(k) process and pre-market approval process?
A. It seems to me the 510(k) process -- and, again, I'm not a regulator so I'm talking off-the-cuff a little bit -- is when another device is already approved, and based on that device they can move the FDA process a little bit quicker in order to -- because there's already been safety and efficacy from the previous product, they can use that as their basis to get another product approved.
Q. So would you agree that that process is a little less intensive for the manufacturer than the full-blown pre-market approval process?
A. Likely, but I have no way of knowing that.
Q. And are you familiar with the process by which the FDA actually scrutinizes the devices before they

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are put on the market?
A. I have no inside information on that, ma'am.
Q. You mentioned earlier that the FDA does its due diligence. What did you mean by that?
A. Well, I mean, it's hard to get any product on the market in America versus in a lot of other countries. And so I think that's -- because of that, I mean, the products that come out are generally viewed as being tested of some sort, that they are safe, that they say what they intend to do.
So when they actually come on the market, as physicians we don't have to go through that whole process and review each step of the way. We just have to assume that the FDA has their regulations they meet and once it hits the market that we should feel comfortable with it. I think if each individual clinician had to go back and review the process that it took for each individual product that comes to market, that would be too onerous. There's no need for that, so...
Q. And you agree that that's the way it should be, that in order for a product to make it through that process, that the proper studies had been done and that there was some showing that the product was indeed safe and effective?

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MR. WALKER: Object to form.
A. I think that the FDA has decided, in many years, that there are certain processes to go through, and I can't disagree with FDA's approval process.
Q. Are you here today offering any opinions on whether or not Ethicon complied with all the FDA regulations with regards to the studies and the data in order to get the products brought to market?
MR. WALKER: Object to form.
A. The FDA approves the products. They're on the market so I have to assume that that was adequate for the FDA. Again, I'm not a regulator; I'm just a clinician.
Q. And that's what I'm trying to get at. Are you going to be offering any opinions with regard to that process and whether or not Ethicon complied with that process?
A. I'm not a regulator so I can't comment on the regulations that go along with that.
Q. So, no, you won't be?
A. No.
Q. Thank you.
MR. WALKER: Can we take five minutes?
MS. BAGGETT: Sure.
(Thereupon a break was taken from 10:39 a.m. to 10:45 a.m.)

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BY MS. BAGGETT:
Q. Doctor, before we went on break, we were talking about your report and we were on page 7. One of the questions we were talking about was the FDA clearance process and whether or not you held any opinions with regard to whether or not Ethicon complied with the requirements of the FDA in getting the product to the market. And you said you're not going to be offering any opinions on that; is that correct?
MR. WALKER: Object to form.
A. That's correct.
Q. And that second paragraph, starting with, "Additionally the device companies are trying to respond to the surgeons and improving the devices they already make. The tendency is to compare the most recent prototype to the gold standard, not the previous methodology, as can be seen with some of the single incision slings, especially the TVT-Secur. There was a steeper learning curve initially, but still with very low side effects and complications."
Do you see that section?
A. Yes, ma'am.
Q. Okay. Are you familiar with what process the TVT device went through with regards to the FDA and being brought to market?
A. Which TVT device?

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Q. Of the Secur. I'm sorry.
A. Yes.
Q. And what process was that? What route?
A. 510(k).
Q. And do you know if there were any studies in human subjects on the TVT-Secur device before it was put on the market?
A. I'm not aware.
Q. You're not aware of whether there was or not, either way?
A. I'm not aware that there were any studies on humans before it came to market. It was all based on previous -- the fact that the sling had been shown to be effective on the TVT and the TVT retropubic and TVT-O.
Q. Are you familiar with the differences between the TVT-S device and the TVT retropubic and the TVT-O?
A. The differences between the devices?
Q. Yes.
A. Yeah, there's differences between the way of placement. There's no difference in the mesh.
Q. With regards to the mesh, it's still the same polypropylene, correct?
A. I think, like we discussed earlier, the Secur is laser cut and -- but it's the same polypropylene

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mesh that I'm aware of.
Q. Are there any differences with regards to how the product is implanted between the TVT-S, the Secur device, and the TVT-R and the TVT-O?
A. Yeah, there's a difference in the way it's implanted.
Q. And what is that difference?
A. The TVT-Secur is a single incision sling, whereas the TVT-O and the TVT retropubic had an exit point. The Secur did not.
Q. And are you familiar or did you read any -- have you read anything, whether it be internal documents or studies, that suggests whether or not the TVT-Secur device initially was rejected because of the dissimilarity between the two devices that were used originally for the predicate device to where they had to add another predicate device in order for it to come on the market?
MR. WALKER: Object to form.
A. I can't recall that.
Q. So your understanding of the 510(k) process, the only thing that a manufacturer has to do is to show that it's substantially similar to a device that's already on the market. Is that your understanding of what that process involves?

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A. Ma'am, I'm not a regulator. I really don't know the specifics of how that occurs. I mean, I really don't.
Q. Would you expect a manufacturer that is using a predicate device to get a product on the market to follow the guidelines and use products that are similar to the product that it's chosen as its predicate?
MR. WALKER: Object to form.
A. Well, they're all slings, so I would suspect that they are very similar.
Q. Would you expect that the data used to get the predicate devices on the market may not apply the same to a product that is not substantially similar to that product?
A. Would you give me an idea about what you mean by "predicate"? I think I understand what you mean, but if you would just define that for, me what you're getting at I guess.
Q. Sure. In the process of applying for a product to be approved to market, the FDA has a procedure where you go through this 510(k) process, and what you have to do is show the product is substantially similar to a product that's already on the market. And I understand you're not a regulator and there's more to it than just that, so I don't want to mislead you.

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My point is, if you're relying on a product you're saying is substantially similar to a product you're putting on the market and you're going to rely on the data that was used in bringing that predicate device to market, shouldn't that data apply equally across the board to the product that you're bringing on?
A. So the predicate device that you're discussing, what exactly are you describing as a predicate device? The device that's in question?
Q. No, sir. The predicate device would be the TVT and TVT-O, which were initially the predicate devices.
A. I understand what you're saying now.
Q. So in order for Ethicon to rely on the data from the TVT device, then that product needs to be substantially similar to the TVT device. Do you agree?
MR. WALKER: Object to form.
A. Needs to have the same use, yes. If you're trying to say that what was on the market for -- well, again, I don't know all the regulations about this, but it would seem to me that that would be a -- there's so many small variations of something, if you had to go through the whole process every time, that would be very cumbersome for the FDA. So I'm assuming that the FDA had to make some type of provision to allow like devices to be

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brought to market.
Now, you know, we're talking about suburethral and midurethral slings. We're not talking about apples and oranges. We're talking about the same type of device. So I guess in my estimation, yes, it is based on what was on there before, which was, again, the same type of mesh, the same placement of the mesh, the same position of the mesh. But other than that, I don't know what the FDA's regulations are about that.
Q. Maybe this will help just slightly and it may not.
A. All right. Good.
Q. I'll do my best. The TVT-S device was smaller than the other two devices; is that right?
A. Yes, ma'am.
Q. And the TVT-S device was stiffer than the other two devices. Would you agree with that?
MR. WALKER: Object to form.
A. No.
Q. The mesh itself was not in any way stiffer than the other two devices?
A. I couldn't tell any difference.
Q. The TVT-S had anchors that were made of a degradable substance where it attached to the body instead of being left open.

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A. Yes, ma'am, that's correct.
Q. And the insertion tools that were used were different than the procedures that were used to insert the other two devices. Is that fair?
A. That's correct, ma'am.
Q. Do you have any opinion whether or not those differences made it necessary that the device should be studied in a different way to see if those differences had any impact on outcomes before the product was brought to the market?
A. Yeah, I mean, I thought about that. And that's been part of my -- when we were going through all this, I did think about that. But I really don't know enough about the regulations to give an opinion. And from a clinical standpoint, if the device has been shown to be safe -- there may be little differences in effectiveness, but if it's been shown to be safe, then I don't know that you really need other studies other than what's already been out there.
Q. Have you read any literature or any internal documents, any of the reliance materials that you reference, in formulating the opinions in your report? Do you recall reviewing anything that suggested that the TVT-Secur device should have been studied more before it was brought to the market?

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A. Did I review records of that? There were internal memos having that conversation, or something of that nature.
Q. And those were Ethicon's own internal communications?
A. I don't remember exactly. I'm assuming so. I don't remember.
Q. Do you recall any testimony as to whether or not -- whether it was Ethicon employees or Ethicon experts that suggested that the product should have been studied or should have had more testing done before it was brought to the market?
MR. WALKER: Object to form.
A. So I don't recall the specifics. I do remember that there was some internal conversations about that, but I don't know who it was that had the conversations. I don't recall any of the details.
Q. And do you recall any studies that suggested that more data was needed on the TVT-S device before it came to the market?
A. I don't remember that either. I don't know that there was -- I know they did testing before just to determine strength and how much was needed to -- how to put the Secur in, but that wasn't done on humans. But I don't recall there being a study or a conversation or

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mandate or FDA went back and said we need more data. I just assume that once they got to the FDA point and it was approved that that was adequate.
Q. You mentioned in this section the fact that there was a steeper learning curve initially. What did you mean by that?
A. Well, with the TVT retropubic and the TVT-O, the name stands for tension-free vaginal tape. So from the first two that were placed, that was the -- the standard was to place it tension-free underneath the urethra. With the Secur, because of the way that you could either place it in a hammock or U-shape, there's a little bit of a different technique there implanting that. And then also knowing that you needed to place it more firmly and securely up underneath the bone into the ligament.
Yeah, I mean, those are the things that initially when I started doing the Secur that I found were a little bit different, but it took all of about five to figure out how that worked.
Q. Did you read any materials in your review for this report that suggested some doctors, the learning curve required more attempts?
A. I believe so, yes.
Q. And do you have an opinion as to whether or not a company that develops a new procedure with a new

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product has any obligation to properly train the doctors using that product before their product is made available to them to use in the patients?

MR. WALKER: Object to form.

A. So, yes. So in order for a new product to be utilized correctly, you need another little -- you need to know the steps, right? And that's what the proctor was to provide to the new physicians. And the technique needed to be modified based on the product. All the slings are a little bit different. I mean the Altis is different than the TVT versus the retropubic versus obturator versus the Monarc. They are all a little bit different, so those little nuances do need to be relayed to the physician.

Q. And you agree that each of these devices that we're talking about, they are not just the device, they are also the toolkits for implanting the device that's part of the package that you get when you go to use these devices. Is that true?

A. The device and the toolkit are what now?

Q. It's part of the package that you receive. It's not just the sling materials --

A. In the operating room you're saying?

Q. Sure.

A. So in the operating room, on the back table the device is opened. Yeah, so the sling and then

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anything else that goes with it to implant it.

Q. So you don't use your own tools to implant the sling?

A. Sometimes. Yeah, in the Secur because you had to use a needle driver.

Q. And that's something that you weren't supplied with by the company?

A. Huh-uh.

Q. And that was part of the instruction that you received in training for the device?

A. Yes, ma'am.

Q. But for the most part, with regards to the TVT retropubic and the TVT obturator, you didn't utilize your own tools to implant those devices?

A. Well, I had to have a scalpel and pick-ups and sutures, So there's -- I just couldn't use what they brought me. I had to use other things for surgery. I mean, it is a part of the surgery.

Q. But as far as the trocars and --

A. The trocars were included.

Q. -- and the cannulas, those --

A. Those were not -- I'm sorry. I cut you off, ma'am.

Q. That's okay.

A. The trocars were single-time use. So they

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weren't sterilized and reused. So each kit had an individual trocar.

Q. And other than the sling -- and I know you said you don't do POP procedures, but other than those type procedures, is a trocar something you use in your normal practice in any other procedures?

A. Yes.

Q. What type of procedures?

A. Interstim, and there's a trocar that passes the wire or the lead underneath the skin from the sacrum over to the battery site.

Q. Is that something that's supplied with the Interstim device as well?

A. Yes.

Q. Now, do you train others how to implant these devices?

A. I do.

Q. And by that I meant the TVT devices, the TVT-Secur, the TVT retropubic.

A. No, I do not.

Q. Are you holding any opinions here today as to whether or not Ethicon's training materials and professional education were adequate with regard to the TVT-O and the TVT-S devices that we're here today about?

A. Yes.

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Q. And what are those opinions?

A. They were adequate.

Q. And did you review all of the materials, the professional education materials, within Ethicon in formulating that opinion?

A. That's part of it, yes, ma'am.

Q. Did you also review internal materials with regards to the development of the procedure as it was laid out in the IFU?

A. I'm not sure I'm following on that. Because what I thought you were meaning was as a surgeon operating on a patient, do you rely on the professional handouts. And so for that I agree. But as a clinician and a surgeon, you wouldn't have privy to those other documents. If you're asking as an expert witness if I'm relying on those things, that's different than just me being a surgeon and operating.

Q. I guess that's where I was going with that. Are you holding any opinions today with regards to the materials that were used to train doctors as to whether that information, those materials, were adequate in this case?

A. Yes.

Q. You do have opinions, and that's based off of --

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A. That's based off everything I saw.
Q. So that would include the materials, the internal Ethicon documents --
A. Uh-huh.
Q. -- and all the training materials associated with the device?
A. Yes, ma'am.
Q. And you've read all of them?
A. I think so, but I couldn't -- I don't know that I've seen every one of them, but all the ones that I saw I think I looked at and read.
Q. And have you heard of -- have you seen what is referred to as a cookbook with regards to the TVT-S?
A. Cookbook?
Q. In the materials you reviewed, did anything --
A. Well, maybe it's the same thing I'm thinking of. But it was kind of like there are like Tips & Tricks? Yeah, I do remember seeing that.
Q. Do you recall whether or not the Tips & Tricks were similar to the instructions that were included in the original IFU, the instructions for use?
A. I believe the Tips & Tricks came out later to help speed up the learning curve.

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Q. Do you have any understanding as to whether or not the Tips & Tricks were put through the FDA process for approval for use with the device?
A. I don't know that.
Q. And do you have any understanding or opinion as to whether or not the Tips & Tricks differed substantially from the IFU?
A. Substantially? No. I think there were some nuance things that after performing it a few times that were obvious that were included on that.
Q. For instance, with regards to the dissection, are you familiar with the recommended dissection length included in the IFU versus the dissection that was discussed in the Tips & Tricks?
A. Well, no. I remember 1.5 centimeters. Now, nobody gets a ruler and makes a 1.5 centimeter mark on the urethra. So it's all kind of an eyeball idea anyway. It may be two centimeters. It may be one centimeter. But that part of things, I don't -- I think of all this -- the idea behind it is to make an incision large enough for the Secur to lay down. And I think that was relayed to the physicians.
Q. So if Ethicon were telling physicians early on that a smaller incision was okay and then found out that that was not actually the case and provided a

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different recommendation in the Tips & Tricks, would you expect that to be something that they would make sure that all physicians were aware of by changing the IFU or advising them, or do you think that every physician was given the opportunity to have the benefit of the Tips & Tricks?
MR. WALKER: Object to form.
A. So to answer your question, so if I was to make an incision that wasn't large enough to accommodate the tip of a trocar, I'd have to enlarge that incision anyway. So I think that was a step that was taken from a -- just to complete things. But from a practical standpoint, when you're inserting the sling in place, it wouldn't take very long to realize that you had to make a little bit bigger incision than you would with the TVT retropubic or TVT-O.
So whether that was necessary and needed to be transmitted to the surgeons, maybe, but in all reality, that was something that was happening already because it had to happen.
Q. Okay. Right after that section we were just discussing, you start the sentence, "When compared to a retropubic TVT, there were some studies suggesting" --
A. Ma'am, can I stop you for a second?
Q. Sure.

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A. What page are you on?
Q. I'm still on page 7, and it's below the section we were just -- it's actually continuing of the paragraph we were just starting, and the part I'm focusing on --
A. "When compared to a retropubic TVT"?
Q. Yes. And what I'm trying to understand is you said -- at one point in the sentence you said "but if it had been invented first would have been a revolutionary improvement over the Burch." Can you explain that section for me?
A. Right. So in my estimation, and the way the literature bears out, is that we had this progression of the way things went was Burch, pubovaginal sling, bone anchor for a time period there, which had its -- definitely it worked, but we were seeing some -- a lot of patients who were having problems with those or were developing quickly recurring incontinence.
And so when we went from here to the TVT retropubic, which was here, we saw -- in my estimation and based on the literature, there was a significant jump in the efficacy and a decrease in the morbidity. The procedure itself took 15 minutes versus before maybe an hour or two, having multiple incisions for a pubovaginal sling. So these people who were in the hospital, they were

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going home. So we saw this change in the Burch and other things to the TVT.

If the TVT-Secur had been the first thing invented, we still would have seen an improvement over what we were dealing with, right? It would have been here. And that aspect of things would have been looked at as, wow, this is significantly better than what we have been dealing with. And it still is, in my estimation, and has been shown to be, better than what we were dealing with. But because these other things were -- already had been on the market, the one thing that Secur had an issue with was initially some efficacy. And that, I think, over time has -- and experience by the physicians has really changed, or did change, but initially there was this small decrease in efficacy versus the TVT retropubic and the TVT-O. But if that would have been invented first, it would have been felt like it was a milestone win.

Q. What is your understanding of the reason that the TVT-S device was removed or was no longer available for use?

A. Why? I think there were a few things that went into it, but I think a lot of it was they just didn't want to continue to -- well, I don't know all the details of it. I don't know all the details why the company pulled it. I think that they decided internally to do that versus

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continue to try to do studies to prove it was effective.

Q. And do you know if the company is currently looking to replace any of those products and currently conducting studies to develop any new products?

MR. WALKER: I'm sorry. Could you repeat the question?

(Thereupon the question was read back by the court reporter.)

MR. WALKER: I just wanted to clarify. What did you mean by "those products"?

BY MS. BAGGETT:

Q. Well, TVT-Secur, for example. The fact that it's no longer available on the market, do you have any knowledge or understanding of whether or not Ethicon is currently working on a device to replace that product?

A. I have no idea.

Q. And based on the fact that -- or were you aware that the FDA was making a requirement that they conduct additional studies on TVT-S in order for it to remain on the market?

A. I was aware of that.

Q. And you know that they were issued a 522 order, and you know what that is?

A. Vaguely, but I couldn't spit it off for you. I couldn't name it exactly, but I have an idea that

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there's a different process of having to kind of re-go through all those steps of getting the product to the market.

Q. And these would be the same type of testing that would be required if you were going to bring another product on the market similar to the one that was removed. Would you agree with that?

MR. WALKER: Object to form.

A. So you're asking me if that's the same process that occurs if a new product is coming to market?

Q. I guess what I'm asking you is the studies that they are being asked to do to prove the safety and efficacy of the TVT-S device in order for it to stay on the market would be similar to the same studies that they would need to do to bring a similar device back to market to replace the TVT-S.

MR. WALKER: The same objection.

A. I don't know.

Q. And that's a fine answer. I'm not trying to pressure you. I'm just wondering if you do know, if you knew whether or not that was the case.

Okay. Let's see. All right. If you'll look down to that next paragraph. I'm actually looking towards the latter part of the sentence where you start -- where you're talking about studies that were done today,

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and in the past and in the future that may be important to a chemist, biologist, or physicians, and then you go into a discussion with regards to these. And I think you meant MSDS.

A. Yes.

Q. For polypropylene suture by Dupont, and that discusses the fact that it suggests a sarcoma was seen in a rodent and perceived to be associated with the polypropylene suture. Can you tell me what you meant by that, that discussion?

A. Well, there was a document that I reviewed that had one case of a sarcoma in a rodent. The correlation was that that could be associated with a polypropylene suture. And what my point was, was that that in and of itself, if you were to tell everybody in the world that this happened, you would get a different -- there would be a different perspective than if you said millions of people have polypropylene sutures in them and none have been reported in the studies to have a sarcoma associated with it. That's a different set of information.

And in my estimation, and based on the data out there, you can't take individual things that in and of itself seem to be applicable to one situation and apply it to a different situation and compare them and say they are comparative. You have to know -- take that

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information as adequate, but in reality has no clinical value. That's what I mean. There's other things that happen like that -- in all of medicine that can't be compared, or apply little clinical value data.

Q. Would you agree that if a concern is raised by the manufacturer of the polypropylene, that you would expect that it would be something that would be studied before it was used in human applications?

MR. WALKER: Object to form.

A. Would you rephrase that?

Q. If a concern was raised by the manufacturer of the actual polypropylene with regards to the use of that material in a medical environment, would you expect Ethicon to at least investigate that concern before using that product in a device that would be permanently implanted in a human body?

A. Would I expect them to? I think that that's -- in this particular situation, no, because there have been, like I said, thousands and thousands and thousands of polypropylene suture placed without any evidence of causing sarcomas.

I do think that if a manufacturer notices there's a problem, they should alert their distributors or people who use their product. Then it's up to the -- you know, based on that, you can interpret it through the scope

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or -- you can view it through the scope of a clinician, but the clinician's viewpoint is going to be different than the engineer's viewpoint. It's going to be different from the manufacturer's viewpoint.

Q. And you mentioned something about the fact that thousands and thousands of sutures have been used in different applications.

Are you familiar with the amount of suture material that is required to comprise the mesh used in the devices we're here today about, the TVT, TVT-O, and the TVT-Secur?

A. The amount of the prolene suture?

Q. Material.

A. I know the weight and I know the -- but I don't know the actual volume of suture that is placed in a sling.

Q. Would you expect the amount of exposure to a product can have a direct correlation to a different outcome when compared to a smaller amount? You take a single suture versus a larger area of the suture, would you expect the reaction in the human body to be the same?

A. There's no way for me to know that. I mean, that's a pretty big jump to be able to say that. I think that it's not necessarily the volume of the suture. It may be where it's placed. It may be how much is placed.

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It may be what it's intended use is for. I mean, a whole host of -- how it's woven together. I mean, to say the volume of a suture would automatically increase the rate of X, Y or Z, unless there's a study on that to let me look at that, I can't say for sure.

Q. And that's kind of where I was heading with it.

The more foreign body material that is introduced into the human body, the more the human body is going to respond to it. Would you agree with that?

MR. WALKER: Object to form.

A. No, I don't agree with that.

Q. So if you have a small splinter in your finger and your body responds with an inflammatory response, is that response going to be greater the bigger the splinter is?

A. Well, the whole site is bigger because the splinter is bigger, but the actual amount of reaction may be the same. It may just appear bigger because the splinter is bigger.

Q. I guess my point is, the bigger surface area means more foreign body present to respond to. Would that --

A. I would agree.

Q. So the bigger the piece of material is in

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the body, the more the body is going to have to respond to address that foreign body. Would you agree with that?

A. I agree that the larger surface area, there's more contact with the tissue, but the actual amount of reaction doesn't increase in that specific spot for that particular piece of mesh or prolene or whatever foreign body we're talking about.

Q. And with regards to the -- you were discussing the difference in mesh weaves and the size. Do you have any understanding of how the porosity of a device affects the surface area that comes in contact with the body?

A. Yes.

Q. What is that understanding?

A. That anything bigger than 75 microns is a large enough pore size to allow ingrowth of fibroblast and macrophages and the normal healing that you'd see.

Q. Have you reviewed materials with regards to the pore size in the devices we're talking about today?

A. Yes.

Q. What materials did you review to get your understanding of the pore size in the TVT-R, the TVT-O and the TVT-S devices?

A. I don't remember the name of the document. I don't recall the name, but I know I looked at it multiple

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times.
Q. What is your understanding of the porosity of the TVT-R, the TVT-O and the TVT-S devices?
A. Those are all 1.37 microns; 1,379 microns. I'm sorry.
Q. Are you familiar with the term "effective porosity"?
A. Not specifically.
Q. Do you -- in your experience with the meshes that you've implanted, you understand that the mesh is flexible, correct?
A. I agree.
Q. And that it stretches. It's elastic in some aspects. Is that true?
A. It is.
Q. Do you have an understanding of whether or not stretching the material changes the porosity?
A. If I took the mesh and I pulled it like this, would it change the form, the size of the pores?
Q. Yes, sir.
A. I would expect so.
Q. Do you have an understanding of whether or not the mesh -- once it has been stretched or put under tension, whether or not the mesh regains the original pore size or if it remains collapsed?

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MR. WALKER: Object to form.
A. I don't know specifically, but I would think if it hits a certain threshold, it would probably not regain its form.
Q. Would that be important with regard to tissue ingrowth once the device is implanted?
A. No.
Q. It would not?
A. The reason being, is there is no physiologic force that can stretch that material in a way that it can't be -- there's no force that can stretch that material that it would change the pore size of any significance.
Q. Do you agree that when the mesh is placed initially in the body that the woman is usually in a position where she is laying down to where there's no tension on the mesh with regards to the organs that it's supporting, the lithotomy position?
A. The lithotomy position. That's the normal position to place it, yeah.
Q. Does the tension that is placed on the mesh change when the woman stands up?
A. Ever so slightly.
Q. And by "ever so slightly," do you have an understanding of how much it changes?

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A. No, I do not have like a number of newtons of cavity that pulls on there. I do know that it's nothing that would be significant enough to change the size of the mesh, because the mesh itself when removed has no real changes in its visible properties.
Q. And that's your understanding, that the mesh pores remain constant after insertion?
MR. WALKER: Object to form.
A. I think the pores can change minimally, but nothing of any substance. And that's due to mainly, probably, from the actual healing process itself. You know, once the healing process starts, then you see probably a -- you know, it gets to a certain point and it's not going to change at all.
Q. But before the healing process starts, do you have an understanding of whether or not the mere fact that a woman standing up or having a body function and putting tension on the mesh, if that has any effect on the porosity before the tissue has a chance to get incorporated into the mesh?
MR. WALKER: Object to form.
A. It's my understanding that that's not enough physiologic force to change any -- have any long-term change in the mesh.
Q. And you said earlier the prolene mesh --

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do you know what the different categories of porosity are with regard to the mesh devices? Have you heard of the term "microporous"?
A. Yes. I've seen studies on type I, II, III, and IV mesh.
Q. And which category do you put the prolene mesh that's used in the devices we're talking about today? Which category does that fall under?
A. I believe that's type I, macroporous mesh.
Q. And do you have an understanding of whether or not the mesh used in the prolene mesh -- do you have an understanding of whether or not the prolene mesh that's used in the devices we're here to talk about today, whether or not that is considered heavyweight or lightweight mesh?
A. Well, describe heavyweight and lightweight to me. I think the weight is dependent upon how you're placing it, how you're utilizing that within the body. So I think the definitions I've seen, different definitions, I don't think there's a consensus on that. I think that's kind of a -- I can't find literature that would say this is a consensus, heavyweight, lightweight. But in reality, the amount of weight is pretty minimal when you're actually placing it underneath the urethra. I really can't comment on heavyweight and lightweight. My suspicion is that it's

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the appropriate weight.
Q. Are you aware of any concerns, either through the literature or within the medical community, that the heavier weight meshes, the more complications you see? Are you aware of anything like that, or the difference between a macroporous versus a microporous mesh and the outcomes?
MR. WALKER: Object to form.
A. I think you're asking me two different things, because a macroporous mesh and a microporous mesh, I think there's studies on there as far as how the patient heals. As far as heavyweight and lightweight mesh, that's more of an arbitrary discussion and, again, one that I think falls short when it talks about midurethral slings.
I think that's helpful maybe when you're talking about hernia repairs or big pieces of mesh that are placed, but when we're talking about such a small area -- and I've done the math on it. I looked at all the different slings and tried to figure what actual weight you're actually seeing when you place it under the midurethra, and there's very significant little difference. I mean, there's miniscule, you know, micrograms of difference when you actually get that piece of mesh and determine the weight and then the length of all the different ones.

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So I'm not -- it's not the heaviest weight, it's not the lightest weight, but it's the appropriate weight to do what it does.
Q. Are you familiar with internal documents within Ethicon that discuss the need for a lighter weight, larger pore mesh?
MR. WALKER: Object to form.
A. Uh-huh.
Q. And are you familiar with the devices that were developed -- or excuse me -- the mesh material that was developed in an attempt to obtain a lighter weight, larger pore mesh for use in the application similar to the devices we're here to talk about today?
MR. WALKER: Object to form.
A. I've seen documents on different types of meshes used from internal documents from Ethicon.
Q. And if there were studies that suggest that a lighter weight, larger pore mesh resulted in safer and better outcomes, would you expect the company to use that mesh if it's available to them?
MR. WALKER: Object to form.
A. Well, you're asking me a hypothetical question, correct? Because that device doesn't exist, or that mesh, that I'm aware of, doesn't exist. So any studies on that would have to be done in the same exact way

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that the TVT retropubic or TVT-O or TVT-Secur was done in order to get results that are comparable. And I don't know those.
Q. Are you familiar with the pelvic organ prolapse devices that were manufactured by Ethicon?
A. I know they exist, and that's about the end of my knowledge.
Q. So you're not aware of what type of mesh is used in those products versus the stress urinary incontinence device?
A. I think along the way somewhere I may have heard there's a different mesh, but I don't know a lot of the details because I never implanted those.
Q. So if the mesh that was used in the pelvic organ prolapse devices was lighter weight and larger pore, would you expect the mesh being used in all of their products to be changed in order to obtain the best possible outcomes for their patients?
MR. WALKER: Object to form.
A. I think that's an assumption that you're saying that that same mesh would provide the same function and efficacy when used for a sling. So I don't know that, again, you can compare the mesh for that product versus the mesh for a sling product unless you had, you know, countless number of patients to compare it. I mean, just

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because it does the job for one particular problem, I don't think you can just assume it's going to be effective in the same -- for a sling.
Q. Would that also be true with regards to the use of hernia mesh in the abdomen versus hernia mesh in the pelvis?
A. Yeah, that's the same thing. Until you get studies that show it's effective and safe, then I think you should always, you know, make sure you're wary of any type of crossover utilization of products.
Q. In the section on page 8 under Tension-Free Vaginal Tape, the second paragraph, mid paragraph, you talk about prolene sutures being composed of polypropylene. They contain antioxidants to prevent the polymer degradation.
In that section, are you saying that you have an understanding as to whether or not polypropylene can degrade?
A. I don't know all the details of why the antioxidants are put in there. I think that, you know, as we discussed earlier, there's nothing that proves that prolene dissolves. Could there be some things that can help it stay sturdier and stronger? Possibly the antioxidants. Again, I'm not a biochemist so I don't know the details of that. But I'm assuming it would just be

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something to help continue to keep its strength.
Q. Are you planning to offer any opinions in this case with regards to whether or not polypropylene used in the prolene devices that make up the products we're here to talk about today, whether or not that polypropylene degrades?
MR. WALKER: Object to form.
A. My opinion is that the prolene does not degrade. And so if you're asking me if I have an opinion about it, yes, I do. That's my opinion. If you're asking me from a biochemist's standpoint what occurs at the cellular level, molecular level, I can't tell you all that. I can just tell you from a clinician, having used prolene suture for many years, doing transplants and other things, that later, when we go back, the prolene mesh is still there. If it wasn't still there, there would be a lot of problems with the prolene -- I mean, the prolene suture, not the mesh -- but the prolene suture would be off the market. So in my estimation, there's no sign of any degradation of or loss of structure of the prolene sutures.
Q. So based on that, is it fair to say that you will be basing your opinions off of your experience with the device rather than your understanding of the science behind the concept; is that correct?
MR. WALKER: Object to form.

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A. Can you be more specific how you ask that question? Are you asking me from a biochemical standpoint am I able to give you the composition of the prolene mesh? If you're asking me that, I can say I'm not here to comment on that. If you're asking me to say when that prolene mesh is outused in patients, what happens to it, does it degrade or not, I can certainly answer that without any hesitation.
Q. I guess that's what I'm getting at. Have you reviewed anything in your preparation to draft a report in this case that gave you an understanding from a polymer standpoint whether or not the polypropylene used in this device is appropriate in this application?
A. I can't comment from a biochemist's standpoint, so I will not provide any insight as far as how this thing is put together; only from a clinical standpoint.
Q. In the section on page 9 under TVT Complications and Side Effects, you talk again about the literature and reviewing it to determine the risks and complications associated with all mesh procedures, and you've listed a couple of studies in this section. Specifically with regard to your discussion on dyspareunia, you suggest that "It's a well-known complication that can follow any vaginal surgery whether mesh is used or not. It is also prevalent among women, especially those that are

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postmenopausal." Do you see where we are?
A. Yes, ma'am.
Q. Do you know if the studies that you reviewed, do they distinguish between the dyspareunia that is experienced by a woman prior to the surgery, or de novo that occurs after she has the device implanted or the procedure done?
A. Yes, ma'am. The studies that I remember reviewing were from the '60s and '70s, and they were looking at overall complication rates after -- and I can't remember, but it was like a hysterectomy, Burch procedure, colposuspension. It wasn't one specific type of surgery. It was all vaginal surgery. And they didn't mention before and after. All right?
So I don't know if it was -- we don't have that. What we do know is what the percentage of patients were after surgery that had a complaint of dyspareunia. We do know from a longitudinal standpoint there's a baseline number of patients who have dyspareunia who don't complain of it, don't share it with other people, but just suffer from it.
Q. So I guess what I'm trying to understand from this section is, are you suggesting that the majority of women that have a procedure are experiencing dyspareunia prior to those procedures?

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A. I can't comment on that, but I would say that not only in that study but in other studies, they do look at dyspareunia rates. And so there's a high -- not a high percentage, but there's certainly a percentage of patients who have dyspareunia rates just like -- well, I'll leave it at that.
Q. Because I think you go into that more in the next paragraph where you talk about atrophic vaginitis occurs in postmenopausal woman can lead to vaginal dryness, cracking. But I guess what I'm trying to understand is that every woman that enters menopause, you're not suggesting that every woman who hits menopause automatically experiences dyspareunia?
A. No.
Q. And you mention that women don't always talk about dyspareunia and may not have talked about it before their procedure.
Is it fair to say the same can be said about women after the procedure, maybe not talking about it at that point either? I mean, is that something that could be possible as well?
MR. WALKER: Object to form.
A. There's two possibilities with that. One possibility would be what you just mentioned. The second possibility was that they were having the dyspareunia

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beforehand. So the studies, even after the years of the midurethral slings, when they started looking at dyspareunia rates, they don't necessarily comment on what baseline of those patients had dyspareunia to begin with.

So there's two points of that that are a little bit mysterious, is how many people are complaining of it afterwards and they're saying -- or had the problem and staying silent, and also how many people had it beforehand that weren't discussed in the study before.

So it's possible. Yes, it's possible. The rate of dyspareunia afterwards is possible. However, in these studies they ask them specifically those questions, if they're going to report them. They're asking specifically for dyspareunia rates. So if they're trying to get an idea about their adverse events and they have a list of things that could happen, one of the checkboxes is it could be dyspareunia, that's one of the things they're going to report on.

Q. And are you saying that in the studies you reviewed that the question was asked both before and after the study was conducted?

A. I'm not suggesting that, because, like I said, some of these people who had dyspareunia after the surgery could have had dyspareunia before the surgery, both before the use of midurethral slings and after the use of

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midurethral slings.

Q. And I'm just trying to make sure I understand, if you know if the questionnaires with that question were asked prior to and then asked again after or not?

A. Every study is different. There's no way for me to know.

Q. That would make a difference to you, as a clinician, in understanding whether or not you're putting your patients at risk for dyspareunia if you had an understanding of whether or not there was actually a presence of it before versus after. Would that make a difference to you in trying to figure out whether or not that's a complication you want to discuss with your patient before her consenting to have the procedure, especially in a young, fairly young, sexually active woman?

A. Listen, I think the way to answer that is this. If we were to see the dyspareunia rates after surgery to be significantly higher than the baseline, I mean, then you would have to assume that those dyspareunia rates are based on the surgery itself. If you see that it's a moderate number, very close to what baseline numbers would be, you would never know if it's just due to the -- there's no way for you to know, and -- unless it is specifically asked before and after, unless there was a big

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discrepancy between what would be expected to be baseline and a high rate. We are not seeing that so we can't assume that in this situation.

Q. So in your review of the literature, you're saying that the rate of the dyspareunia that comes after the surgery is low?

A. Yes.

Q. And do you know, based on your review of the literature, whether or not the dyspareunia remains chronic and indefinite after the procedure or if it improves after time passes?

MR. WALKER: Object to form.

A. They have done longitudinal studies on them. I'd have to go back and review the literature to see exactly. But it's in my mind that it tends to get a little bit better, but not substantially better over time, unless treated with other like topical agents, estrogens and things like that.

Q. Let's turn to page 10. We're in the section entitled TVT-O.

A. Yes, ma'am.

Q. And you discuss the development of the TVT-O procedure was sparked by rare but significant complications with valve preparations in the middle of the paragraph, but the second small paragraph.

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So your understanding from the review of the literature is that the TVT-O device was meant as another option to improve upon some of the adverse experiences surgeons were having with the TVT retropubic device?

MR. WALKER: Object to form.

A. From my understanding, the obturator route of placement of the sling was sparked not only to decrease the risk of what's listed here, but also to help improve voiding postoperatively and to decrease the rate of transient retention. It also was sparked by -- there's blood vessels behind the pubic bone that can be hit and that low risk of retroperitoneal hematoma. So it was trying to improve upon an already good product.

Q. On page 11, the complications and side effects, you discuss the studies that compare a retropubic route to the transobturator route and the fact that the obturator exhibits more neurologic symptoms, mainly consisting of leg weakness of the upper legs. Do you see where that is?

A. Yes, ma'am.

Q. And then you go on to quote the Richter study with regard to those adverse events. And then in the next section you mention most leg weakness is short-term from placement of the trocar through the obturator internus

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muscle. And in this section I was wondering what study you were basing this information on, because you also go on to discuss the procedure with regards to the 45 degrees versus 90 degrees, and I wanted to see if I could get an understanding of where this information came from.

A. Which part are you wanting to know? So the 45 to 90 degrees part?

Q. Well, the fact that most leg weakness is short-term, what did you base that opinion on?

A. Well, because there's some longitudinal studies that look at leg weakness or pain initially and then that over time is -- the rates of that actually decrease so, you know, that actually is just transient. So that's part of it.

Also part of it is from experience placing the TVT-O. And then just the shear volume of data that's out there. I don't know if there's a specific study. I do remember one longitudinal study looking at 12 months, 24 months and seeing if there was a decrease in leg weakness and pain.

Q. But you're not aware of any longer-term studies that suggest that the leg weakness continues?

A. I am. I just can't quote it to you. And it tends to decrease over time.

Q. Do you know of instances where it has not

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decreased over time but it has increased based on reports or studies you reviewed?

A. That it's increased over time? I've not seen that.

Q. Going on to the section with regards to the section where the handles had to be dropped from 45 degrees to 90 degrees before passing through the foramen, are you basing this on Tips & Tricks that you learned with regards to the TVT-O or was this something that was in the IFU, or do you know?

A. I believe that was in the IFU, but I would have to go back and review specifically. I do know that there's -- they may not say it specifically, but that's the idea behind the placement, was dropping the handle. That's a key technique part.

Q. Now, in the section near the bottom of page 11, you're continuing to talk about some studies that you referenced above, the Cheng study, the Serati study. You start the paragraph, "These findings demonstrate that while nerve injury is a potential and warned about risk of the TVT-O, long lasting pain associated with TVT-O is very rare. While it is possible that misguided trocars could injure the obturator nerve or even in some cases the pudendal nerve, such injuries are almost impossible if the TVT-O instructions for use are properly followed by the

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implanting doctor."

My question is, if there is a patient that experiences an injury with regards to the obturator nerve, it's your opinion that it's the implanting doctor, his failure to follow the instructions for use that results in that complication?

A. Yes.

Q. Do you have any opinion with regards to whether or not the fact that it's a blind passage of sorts has anything to do with the ability of the doctor to follow the instructions in the IFU?

A. So you're asking me does it make it more difficult because it's a blind procedure? The answer to that is that if you follow the instructions, that it's been shown in anatomy, cadaveric labs, that you're going to be way away from any nerves. And so the only way to -- you know, you can feel your landmarks. You can feel where you're going with the procedure. So it may be partly blind, but it's also a tactile procedure as well. And so if you're just -- you would have to be extremely way off mark to get anywhere near the nerve or artery or vein.

Q. Are the landmarks you discussed, described just now, do they change from patient to patient as far as -- so if a woman is small stature versus larger in stature, does that affect the landmarks and the path of the

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device?

A. Not substantially.

Q. What do you mean by "not substantially"?

A. Well, externally there may be a little bit more size, but the actual anatomy of the pelvic bone doesn't change substantially. So once you know where your landmarks are, you should be able to follow the path in without any trouble. So even though the patient may be small or big, certain landmarks are consistent. And you don't see, you know, wide variations in pelvises. I mean, from child to adult there is, but from one adult to another, there's not a wide variation. You don't see a change in where a nerve or vein go. I mean, anatomy is anatomy. So there might be some subtle changes, but nothing substantial.

Q. And that would have no affect on the ability of a doctor to follow the instructions provided with the TVT-O device in your opinion?

A. Correct.

Q. So in any of the cases where there were reports of groin pain related to the passage of the trocar through the -- I guess it's the --

A. Obturator internus and obturator membrane.

Q. Correct. So any injury that would be sustained by a patient in those areas following a procedure

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would all be because of the doctor's error?
MR. WALKER: Object to form.
A. So I would expect there to be some pain in that area initially. It doesn't mean it was a defective product. It doesn't mean that the surgeon did anything wrong. Because you're placing a needle through a membrane and then some muscle. So, you know, I would expect there to be some transient groin pain. I mean, that's part of having surgery.
Q. And do you have an opinion whether or not the actual mesh that is fed through the tissues and muscles that you were just describing, whether or not the fact that that foreign body remains behind in that area has anything to do with the continued groin pain or any of the effects we were just discussing?
MR. WALKER: Object to form.
A. I have not seen data to support that.
Q. Would you expect for there to be situations where having a foreign body in that area long-term with movement, such as running or being active, could potentially manifest itself as groin pain related to the placement of the mesh?
A. I think any surgery in that area could, but my problem with that premise is that if that was the case, then every woman who ever had that implanted should

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have that problem, and that's obviously not the case. So any woman can have groin pain from that surgery or she could have groin pain from a non-mesh-related surgery. Whether it's related to the mesh internally, you know, again, I haven't seen the data on that.
Q. Do you know if there are any studies that look at specifically the activity levels of a woman receiving an obturator device versus a retropubic device where that was actually analyzed and discussed in the study?
A. I can't recall one being set up to discuss activity levels after a sling. I would -- you know, everybody's activity level is different to begin with, so how can you really compare that? It would be a tough study to compare.
I think that more than anything you're looking at are the people in general living their lives and doing the things they want to do without complaining of groin or leg pain. And that would be shown in the studies.
Q. Have you reviewed any documents in preparation for your report in this litigation, internal or otherwise, that suggests that there was a concern for using the TVT-O device in women who were active in sports that would include a lot of running or activity --
MR. WALKER: Object to form.

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A. An internal document?
Q. Yes.
A. I can't -- I don't recall seeing one, no, ma'am.
Q. Okay. If we could turn to page 12.
MR. WALKER: Could we take five minutes? It's noon.
MS. BAGGETT: Sure. That's fine.
MR. WALKER: Just so we're clear, tell me if you have any issues with this.
We're doing a five-hour deposition that is covering both TVT-O and TVT-Secur. We're not doing two separate depositions essentially. Is that fair enough?
MS. BAGGETT: That's fair.
(Thereupon a break was taken from 11:59 a.m. to 12:08 p.m.)
BY MS. BAGGETT:
Q. Doctor, before the break we were talking about the TVT-O device and some of your -- sections of your report. I think we left off on page 11. And going to page 12 from page 11, you start the discussion about the Cochran Review, and you're discussing the 2015 review by Ford, and then on 12 you move over to discuss the more recent Cochran Review. And I noticed you didn't cite it,

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so I was just wondering which review you were relying on there.
A. Well, let me look at this here. You're talking about which Cochran Review is this last one?
Q. Yes, sir.
A. I assume it was the most recent one, but I'll have to look and see here.
Q. And at least for the purpose of drafting this report, where you have referenced a study, is it fair to say that you read the study at least in its entirety and not just an abstract or --
A. That's correct. If it's in here, then I read more than just the abstract. Let's look and see here.
Q. Actually, if you're saying the most recent, I'm going to accept that as -- I don't want you to have to --
A. Thank you.
MR. WALKER: I can tell him which tab to go to, though.
MS. BAGGETT: Understood.
BY MS. BAGGETT:
Q. I did have trouble finding one in the section under urinary retention, the Johnsson Funk I think. I was looking for that study. Is that the correct spelling and such? Can you just verify that?

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A. It might be a hyphen in between there. I may have it in here, too. Let me look and see. I'll tell you what. If I can't verify it now, can I get back and update you?
Q. Certainly. That's fine. So if you'll just note that one and the Funk one referenced above of 2013, if you could just confirm that both of those, what the actual --
A. Can I write on this?
MR. WALKER: Yeah. Well, no, actually, that's the one that's been marked.
MS. BAGGETT: You know what I can do is -- I have an extra copy he can use.
THE WITNESS: Thank you.
MS. BAGGETT: All right. So we'll move on.
MR. WALKER: Maybe I can help with that. I think that might be a typo in terms of Jonsson. It's J-o-n-s-s-o-n Funk.
MS. BAGGETT: J-o-n-s-s-o-n. And is it hyphenated?
MR. WALKER: It's not in the study.
MS. BAGGETT: Is Funk, also by itself, the proper cite for the one above it?
MR. WALKER: I don't know.

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MS. BAGGETT: That's fine.
BY MS. BAGGETT:
Q. Okay. Now, on page 13 of your report you talk about professional society statements. And you've read each one of the statements or the guidelines that you reference in your report in full. Is that fair?
A. At one point in time I have, yes.
Q. And in doing so, did you also look at the studies that were cited in each one of the documents produced by these societies, or had you seen it before on reviewing the society documents?
A. I didn't go through each one specifically individually, but a lot of them I recognized or knew I had read sometime in the past, so I didn't go back through each one to review each study.
Q. And the reason I ask that is because in the third paragraph starting in 2015, you're talking about the American College of Obstetricians and Gynecologists in conjunction with the American Urological Society, and you referenced that they reviewed the literature and issued a statement based on level of data available, Level A recommendation based on good consistent scientific evidence. And I wanted to make sure that you -- if I understood whether or not you had independently verified that that was actually the type of evidence that was

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used --
A. Oh, okay.
Q. -- or if it was something you relied on the position statement to tell you.
A. So on this one specifically, I went back and I reviewed the -- I didn't read the whole study, but I did go through to see what they recommended as far as Level A and so on to see if I either recognized the study or saw that it was a high-powered study. And if I wasn't sure, I'd go back and reviewed the abstract quickly to make sure that it was something I could feel comfortable with. Did I read every bit of every study? No, I did not.
Q. And by doing the abstract, or reviewing them in the manner you just described, were you able to discern how many of those studies were long-term versus short-term in your review?
A. Sitting here now, I can't give you that. I can't recall.
Q. That's fine. At the bottom of page 14, you reference five other societies and organizations joined AUGS and SUFU in support of these statements. Are they listed above or are they an additional five societies that also -- I was wanting to make sure I understood what the five other societies were.
A. No, I would have go back and review. I

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think there was a mention of other small societies and I didn't have the acronyms for each one of those. So I can go back and review that and get that.
Q. Sure. And we can move on. I don't want to hold up to do that. We can make a note to reference what the five other studies were here. And we'll move on to TVT-Secur.
Okay. In this section, under Design, you reference the fact that "Other companies were developing their own type of single incision sling and cumulatively, they were described as 'mini slings.' I believe that the TVT-Secur was safe in design and base this opinion on my review of Ethicon documents, my discussions with colleagues and my review of the medical literature."
So is your opinion with regards to the actual design of the device or on its application in your practice?
MR. WALKER: Object to form.
BY MS. BAGGETT:
Q. I guess what I'm trying to say --
A. Is that two separate issues?
Q. Well, let me see if I can make that question a little better. I may need to break it down.
Okay. So I guess what I want to get an understanding of is the opinions that you hold in your

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report. Are you an expert -- are you holding yourself out as an expert on the design of medical devices?
A. Only as they apply to how they are used when the final product is available and used on a patient. But the actual engineering, I wouldn't.
Q. So you've never designed a medical device in your practice?
A. No, but I have been involved with a think tank, help improve designs for the Medtronic Interstim device. I've helped with that, but I haven't physically engineered any type of sling device.
Q. Are you familiar -- as part of your review in offering these opinions, did you make yourself familiar with the standards a manufacturer must follow in designing a mesh product?
MR. WALKER: Object to form.
A. So you're asking me if there's a certain set of guidelines that manufacturers have to follow? No, I'm not aware of how that process goes on.
Q. And are you aware of any standards or guidelines that must be followed in order to submit a device, medical device, for approval or clearance through the FDA?
A. You lost me on that. Say that again.
Q. I'm just trying to understand if you

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are -- in addition to being familiar with how a company manufactures a device, are you familiar with the regulations surrounding designing a device that must be met in order to satisfy the FDA in order to get the product on the market?
A. Is that not similar to what we discussed earlier about the 510(k)?
Q. It's similar to it, but with particular regards to the design. So there's safety and efficacy things that can be done --
A. Right.
Q. -- but then there may be some --
A. My knowledge of these devices comes from going to meetings and talking to the different doctors who have been involved in the different designs, or going and reading the internal documents. But in no way, shape or form have I ever been involved in the day-to-day process of designing these things.
Q. So is it fair to say that you're not familiar with the failure modes and effect analysis and its role in the development of the device? Do you know what those are?
A. I'm not familiar.
Q. So you didn't review any procedures from Ethicon's internal documents with regards to design, the

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designing of this device?
A. I did read those.
Q. You did?
A. Yes.
Q. And what, if anything, did that, in your opinion, make you qualified to opine about with regards to the design?
A. So from the standpoint of all the prototypes, no. But once it gets to a certain prototype and it starts to become -- when the device is actually to the point where it's going through the different studies, whether it be human or animal, at that point those studies are important to me, and so I would give an opinion based on that.
Q. Do you know what a DDSA is?
A. DDSA. I'm not familiar.
Q. And FMEA? Those are not acronyms that you would use routinely in your practice?
A. No.
Q. Do you have an understanding of whether or not when Ethicon was designing the TVT, the prolene mesh that was used in the TVT, the TVT-R and the TVT-S, if the mesh was designed to rope?
MR. WALKER: Object to form.
A. Well, the mesh was not designed to rope.

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You're asking me if it was designed to rope?
Q. Do you know if the mesh was designed to rope?
A. I think the idea behind the mesh was for it to lie flat, but I don't know that there was any studies to look at roping on mesh.
Q. Do you know whether or not the mesh was designed to curl?
A. I can't comment on that, but in reality we all know that it curls.
Q. Do you know if it was designed -- that the mesh in the prolene -- do you know if the mesh -- let me just start over on that one.
Do you know if the mesh used in these devices was designed to fray?
A. Was designed to fray? I'm not privy to that information.
Q. Do you know if it was designed to lose particles?
A. I'm not aware of any documents on that.
Q. Do you know if it was designed to shrink?
A. No. I'm not aware of any studies that were designed to look at shrinkage of mesh.
Q. Do you know if the mesh was designed to deform easily?

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A. I'm not aware of that either.
Q. Would you agree that the things that I just asked you about, each one of these, the roping, the curling, the fraying, the particle loss, and shrinking and deformation, that these would be considered unwanted or unintended consequence of the mesh, whether they have clinical impact or not?
MR. WALKER: Object to form.
A. No. It depends on what they are using them for. Some of the things you're saying -- you lumped a bunch of things together. I don't know that, A, number one, that some of the things you described are of any negative consequence. B, I think it depends on what you're using the mesh for at the time it was studied.
Q. And today, for the purposes of today's discussions, we're talking about the use in the TVT-R, the TVT-O and the TVT-S devices. And my question is specifically whether or not you agree if those qualities would be unintended with regards to the design of the devices, whether or not it has a clinical impact or not?
MR. WALKER: Object to form.
A. What you're describing there may -- well, I don't know that it has a clinical impact. If it were to have a clinical impact, hypothetically, then I don't know of it. And I don't know of the ramifications of

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determining that and then what the next steps are to rectify it.
Q. But even more succinctly, do you agree that these conditions were not the intended consequence in designing the mesh?
MR. WALKER: Object to form.
A. I can agree with that.
Q. While we're on the subject of your opinions, are you going to be offering opinions with regard to warnings that were provide by Ethicon with regards to the products at issue in this case?
A. Yes.
Q. What risk information are medical device companies required to put in their IFUs? Are you familiar with the requirements?
A. Their requirements?
Q. Uh-huh.
A. Adverse events that are reported in the literature I suppose. I don't know if there's a way that the IFU is set that has to be met, but...
Q. Do you know what the industry standards are governing warnings on medical devices?
A. I'm not aware of how those industry standards are set. I do know that from a -- again, this is all from a clinician standpoint, how we perceive and look

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at those warnings.
Q. And that's kind of what I'm trying to get at. As far as in your clinical practice, the way that you perceive the warnings versus whether or not those warnings met the expectations of the industry in complying with regulations and standards.
A. So you're taking that question and assuming I know what the standards are. I think they met the standards, yes.
Q. And you know what those standards are?
A. What I'm saying, I'm speaking from the standpoint of a clinician what those standards would be. I'm not involved in, again, regulation, so I don't know how those things are set. Do I think the IFU is acceptable in its either current or prior form? Yes.
Q. Have you, in your review and in drafting your report, read any testimony from Ethicon employees regarding Ethicon's position on what needs to be in the IFU?
A. Yes.
Q. And do you have an opinion as to whether or not there was some conflict between the employees at Ethicon whether or not something should have been in the device that never made it to -- or should have been in the warnings that never made it to the warnings?

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MR. WALKER: Object to form.
A. I don't know of -- I do know there were conversations among Ethicon representatives about certain items. Again, from a clinical standpoint, that's kind of a ticky-tack question. Most of those items they're discussing are already well-known complications, side effects, that we tend to deal with with any pelvic surgery. To me, I glanced through those, but in practice it's not much of an issue.
Q. Do you agree that physicians should be made aware of all the significant safety risks that are associated with the product via the IFU?
MR. WALKER: Object to form.
A. I'll just say this about the IFU. The IFU, to me, needs to be in there because it has to be in there. But I don't rely on the IFU. I don't know other surgeons who rely on the IFU. I mean, to me, that would be like relying on your builder to look at a printout of how to put each board together.
There are certain inherent things that are in the IFU that I think are silly and don't need to be there. For instance, it says "Don't operate on people who are on anticoagulation," or "Make sure you sew up your incision." So the IFU, from a clinician's standpoint, is very -- it has to be there, but it's not something that we

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rely upon.
Q. In our discussions earlier today we were talking about how you were trained on the devices, and you mentioned that the earlier devices you learned in residency, through your residency programs, and that with the TVT-S device you actually took the professional education courses provided by Ethicon. Do you recall that conversation?
A. Yes, ma'am.
Q. Do you have an understanding of whether or not -- and I know that you just recently testified that you don't rely on the IFU -- do you have an understanding whether or not the people that you learned the procedure from, whether or not at some point they may have read and relied on the IFU in relaying information to you?
A. Well, I don't know that I testified exactly that, said I don't rely on the IFU. But it's not a critical -- if I said that, really, my point of saying it is it's not a critical part of a clinician's decision-making process. It can be helpful in certain circumstances, but in reality we don't -- you know, physicians don't look at that every time that we perform a procedure. Are there other physicians who may look at that before? I have no way of knowing. I have no way of knowing the people that I've trained from, whether they

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looked at that or not.
Q. I guess what I'm getting at is who would be in a better position to know all of the fine details of the procedure than the designers of the device and the procedure?
MR. WALKER: Object to form.
A. So who would be better at knowing that than the designers? Are you talking about the manufacturers?
Q. Uh-huh.
A. Well, isn't it kind of a combination of the manufacturers and the physicians to come up with that?
Q. Well, and, actually, I think the manufacturers employ physicians that assist with this. But I guess what I'm saying is, you learn what you learn from med school. At some point someone has to be taught -- number one, shown that there is such a device and then shown how to properly use the device, even if that information passes from preceptor to preceptor to preceptor.
I guess what I'm trying to understand is, who would be in the best position to know how to properly perform that procedure than the manufacturer?
A. I understand what you're saying now. Okay. So there's multiple parts on the IFU. The part

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that's probably the most helpful may be the step-by-step way of putting the device in, the utilization of it. The things that actually from a standpoint of -- I think it's kind of a little bit -- I don't know if not necessary is the right word, but of really no practical importance; you know, what patient is operated on, how long postoperatively to do things. I mean, that's a little bit insulting to my intelligence to say that I went through all that training to have somebody tell me that I have to tell the patient they must wait four weeks before intercourse after having the sling procedure. And there's a lot of stuff like that that's in there, but of any to no practical use.
So that thing that is practical useful is the actual, you know, where do my hands go, what do I need do to put this in. But the other part of it is, I mean, it's already well-known, it's already something that's reported in the literature, and it's not something we gained just from the IFU.
So to answer your question is, there's no other person that's better than all the physicians who use it and the company that makes it combined together with all the literature to come up with these IFUs.
Q. I don't mean in any way to insult you and your intelligence with my questions.
A. You're not insulting me.

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Q. I just want to make sure that you understand that I've got my job to do to ask these questions.
A. No, ma'am, I don't take it from you at all.
Q. And I do understand where you're coming from with the fact that certain things that are understood in your practice may not be as necessary to state in the IFU, but would you expect that the more important the information is that the more -- I have a tendency to get my whole thought process off. So if that is common information that every doctor should know, and you're not going to pay any attention to it when you go and review it, certainly if there's something that's not common, that would be something that you would expect to learn from the manufacturer of the device and not wait until the studies that could be many years down the road come out that suggest there's a problem, if they knew at the time the device was manufactured. Do you agree with that?
MR. WALKER: Object to form.
A. That's a pretty convoluted question.
Q. If you want me to restate it, I will, or do you think you understand it?
A. I think I understand it.
Q. Because I don't want you to guess. I

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don't want to confuse you.
A. Right. So are there things in there that need to be stated that aren't well-known otherwise? I mean, by the time that these things are made or put in, there's already data on it, so you have to come up with that information somehow, right? And that data -- I mean, is there any data that we don't see that's out there? I wouldn't think there's very often that that occurs. But anything that I think is important could be put in there, but it could not be put in there.
Again, as surgeons we just don't use that. I mean, it's not a practical part of daily operation. I get an IFU every time that I put in an Interstim. I've not looked at one in years. I don't understand why people feel like that's the Holy Grail of what we do as surgeons. I mean, we learn how to do a procedure. Once we learn how to do the procedure, we already knew the risks and benefits beforehand, we know what the potential side effects are afterward. I mean, all these things can happen. We know anything can happen with surgery. So, you know, the IFU doesn't really play a big role in this.
Q. I guess what my distinction is, certainly between the things that you know or should know as a surgeon, and more focused on the things that you may not have the ability to know because as far as the literature

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available to you, it hasn't made its way into the common knowledge.
A. Well, I think things like -- for instance, if I put in a sling and they noticed that patients were having blue vision, I'd want to know that. That's something that doesn't make any sense. That's completely off the mark.
But anything that has to do with vaginal procedures, bleeding, pain, et cetera, et cetera, et cetera, that's not a big surprise. What would be a big surprise is if they said that your right knee would hurt or maybe your left elbow would hurt. I mean, those are off-the-wall things. Yeah, those things I would want to know, but anything other than that, it's all common knowledge.
Q. So for instance, with regards to the TVT-S device, we discussed earlier about the fact that it was laser cut.
A. Okay.
Q. If the manufacturers of the TVT device understood that the laser-cut mesh had a propensity to cause more frequent and more severe erosions or exposures than the other devices, would that be something that you would expect that they would -- whether it be in the IFU or in the form of some other communication -- make you aware

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of as soon as they knew about it?
MR. WALKER: Object to form.
A. So by stating that you're wanting me to assume that's the truth, that there's a significant difference in the two? Because I'm not going to answer in a way that's going to tell you that I think there's a difference significantly between a TVT-O --
Q. I'm not asking it in the way that you --
A. If you are asking hypothetically --
Q. If there were documents that suggests --
A. If there were documents, okay.
Q. -- that Ethicon was aware of that suggest that the device had a greater risk of erosion than the mechanically-cut devices, and they knew that before they offered that device, do you feel like the company is obligated to make you aware of that before --
A. If there's a huge --
MR. WALKER: Hang on a second. Did you finish your question?
MS. BAGGETT: -- before you use that device in one of your patients?
MR. WALKER: Object to form.
THE WITNESS: If there's an enormous disparity, then I think there's something that needs to be said. If it's an inconsistent, small,

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then I think that there would be -- the margin of error or the -- I guess I'm blanking on what I'm trying to think of. But the potential that happens by chance could accommodate for that. But if there's a significant change, then that would be something that we would want to look at.
BY MS. BAGGETT:
Q. And I understand that as far as this field of practice goes, you're at the upper end in a urologist's understanding of female anatomy and the procedures and the techniques, but as far as someone on that bottom layer -- and I think you also mentioned to me earlier that at least unique to Knoxville, the gynecologists don't perform the same stuff that the urologists do, they refer them to the urologists.
So in situations where that's not the case, this is not the norm, and you've got a doctor who is not as well adept at the procedures and the anatomy and the understanding of the disease processes, do you feel that there's any obligation on the manufacturer of warning in a way that helps that type of doctor understand the seriousness of some of the adverse events, if only to allow them to have that conversation with their patients when deciding whether or not to use the device?
MR. WALKER: Object to form.

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A. Well, that's a thought. And I guess that's something that the individual physician probably needs to come to terms with, is do they feel comfortable doing that procedure or not. I mean, there's certain procedures I don't feel comfortable with and I'll send off to others. But, you know, that's part of the whole -- you're asking me is that -- if you didn't know about a certain problem, and you were going to go ahead and perform a procedure, would that be something that you may have not done if you had known there could be a problem to begin with? Is that what you're asking me?

Q. Yes, sir.

A. I think what you're insinuating there is there's some type of significant discrepancy between what's known and what's true, and that would be hard for me to really believe.

Q. And I'm not asking you to agree with me on any given point whether or not there is such a thing, because we don't have time to go through all the studies and all the internal documents for me to show it to you, and I know you're limited on what you can glean from the few documents I've even shown you today. Certainly that's one document in millions.

But for the sake of argument, as I said, it's only if that were true and there were events that were

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serious enough that a doctor might reconsider using it, especially in a certain population of patients, or at the very least would have had that conversation with the patient and allowed them the opportunity to decide, that would be something important to relay to those doctors?

MR. WALKER: Object to form.

A. You know, I think that -- I'm trying to put myself in the position of those physicians. And, you know, if it was a new procedure that just came on the market and there was no precedents before it, it was completely new, I can see that. But when it's just a variation of what's going on before, I think you already have an idea about what to expect and not expect and side effects and complications.

So at that point, you have to make the decision. And I think you have to be honest with the patient and say, look, I haven't done many of these procedures; if you would rather go see somebody else who has, we can do that. But it's the conversation. And I think if it's a completely new procedure that's never been on the market, completely different than anything else, I can see that. I think in other ways, as a physician, you can assimilate all that information fairly rapidly and come to your own conclusion.

I do think there's some -- you know,

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obviously, the companies are trying to make it easier on the physicians and, therefore, the patients. And so they don't want to -- they don't want to hide things from the physicians, because if they start having problems, they're going to have a big backlash against that product and they are going to lose confidence in that product. So I think there's got to be a very open dialogue. I would expect the company would want that, because, otherwise, there would be a mutiny.

Q. And you were just describing a situation where a product is new to the market. With regard to the TVT-S, are you aware of any discussions in any of the documents that you've reviewed or in any of the testimony that you've reviewed in preparing your report today of whether or not one of the problems with the learning curve situation with the TVT-S device was because doctors were trying to rely on the procedure they had been taught with the TVT-R and the TVT-O and that procedure was different enough that it wasn't flowing perfectly with the way that this procedure had to be performed, or do you have an opinion at all?

MR. WALKER: Object to form.

A. Yeah, it would be hard for me to really comment on how that all -- I mean, each individual physician's ability to do that. I mean, it would be a

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guess on my part.

Q. And if you knew that -- and I think we may have talked about this before, so if I'm repeating, I apologize. I'm just trying to make sure I've got it clear. But if Ethicon was aware of enough of a difference in a procedure that was subjecting women to additional complications and/or failure of the device because of the lack of proper training or information with regard to the differences in the approach and the technique, do you feel that it's their responsibility to make sure that that is related to the doctors that are going to be using the device?

MR. WALKER: Object to form.

BY MS. BAGGETT:

Q. Do you understand what I'm asking you?

A. So you're asking me if the complication occurs or if there's a change in the procedure enough, that that needs to be relayed to the physician? Possibly. This is just so -- you know, I think that it is a new procedure, or it was a new way of putting it in, and so there are little nuances there that I think very quickly could be disseminated to the physicians, either through the work of their sales reps or what have you, or the proctors. And that could be something done very easily, just a phone call or e-mail saying, hey, make sure you put this in this way,

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a little bit tighter than normal with the obturator and the retropubic. I think that could be a very easy way of disseminating that information.

Does that answer your question?

Q. It does. Do you know who Dr. Lucente is?

A. Dr. Lucente? I've never met the man.

Q. Have you read about him in the materials that you reviewed in drafting this report?

A. Yes, I do remember him, but I'm going to have to go back and review precisely what his role was.

Q. And I'll save you some trouble. I just want to know if you recall reading anything that suggested that even Dr. Lucente -- who I'll represent to you was one of the KOLs with Ethicon -- whether or not you read anything suggesting he was having trouble with the learning curve as well when he first began using the TVT device?

MR. WALKER: Object to form.

A. Yeah, I don't recall exactly.

Q. And that's fine. You reference on page 16, in the second paragraph, "Other studies showed inferior cure rates of the TVT-Secur and the TVT-O or TVT-retropubic," and you chalked that up to the learning curve for the placement of the sling because the only variable was the surgeon. Can you tell me exactly what you meant by that?

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A. Sure. So, I mean, it's the same product and it's the same -- you know, we'll go back to your IFU you discussed. It's the same women. They are not some different type of women. So how can you explain the difference between some products being as effective as other products? Well, I mean, if you're getting good results in one area of the world, but a completely different area of the world doesn't, then that means that there's an issue with the way they are putting it in. I mean, there's no other variable. And I can't explain it. I don't know. But, I mean, who knows what their training is, who knows how they work in Australia and Germany. I have no idea. If they are experienced implanting these things, I have no idea. That's the only variable.

Q. And you go on to suggest that "Ethicon's outreach to surgeons and their communications of surgical insights to the medical community following the release of the TVT-Secur demonstrate the company's responsible efforts to ensure the TVT-Secur was being properly implanted across the board. Their warning in the TVT Secur IFU that under-correction or incorrect placement may result in incomplete or no relief of urinary incontinence was appropriate."

And based on what we discussed earlier, can you explain this to me?

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A. Well, they have to place it in there, right? I mean, that's part of what they have to do. They have to say that. But the other part of it is, again, they want a product that is effective and they want their implanters and their patients to have good results. I mean, if you make a crappy product, it's not going to -- you're going to have a hard time with having the physicians trust you, right?

So if they noticed they were having some issues, they could have done one of two things. They could have just said, Well, those doctors don't know what they were doing, they just need to read the literature, or we can actually encourage them with some little tips that will improve the efficacy of what we're already doing.

Q. And is that what you meant by their warnings in the TVT-Secur IFU and their outreach? Are you saying that Ethicon undertook efforts to make doctors aware of these?

A. I believe so.

Q. And you base that on the documents that you reviewed in preparation for this report?

A. Yeah. I mean, there's a lot of ways to go about improving things, and so they did take steps to try to improve it.

Q. And what steps do you recall from your

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review, if any -- what do you recall from your review of the steps that they took to reach out to the surgeons?

A. Well, the Tips & Tricks is the main one, and that gets relayed, again, to the guys in the field who are in there operating with the surgeon, just reminding them of the simple facts.

Q. If you'll go with me to page 17, at the top. Although it's the middle of the paragraph, I wanted to focus on the first sentence. It says, "relatively few side effects as thigh pain was virtually eliminated and retention rates that were much lower. It appears that if this technique was developed prior to the TVT or TVT-O, that the enthusiasm would have been much greater."

A. Hold on.

Q. It's back to what you were saying before about the innovation --

A. I'm not sure where -- do you know -- which paragraph are you on?

Q. Top of 17. You can read the whole paragraph. That was what I was trying to understand, is --

A. Okay. I understand now. I see.

MR. WALKER: Was your question just for him to explain it?

Q. Well, yeah. I wanted to know that you -- let's see. The fact that it appears if this technique was

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developed prior to the TVT or the TVT-O that the enthusiasm would have been much greater, and I just wanted to get an idea what you meant by that.

A. Well, it goes back to what I said earlier. The bar was set so high when the TVT Retropubic and TVT-O came on board that people saw cure rates and success rates and less morbidity and return to work and those type of things. They saw that so much faster that you kind of lost perspective of where you were in 1990. And if the TVT-Secur had been the first product on the market, and had the same efficacy that it did when it was launched, people would say, oh, man, what an improvement from what we had before, we can now cure incontinence with a small incision, people can get back to work the next day or a few days later, minimal pain medicine, you know, the voiding dysfunction is really undisturbed, incontinence rates are improved, we would say that's a significant improvement over what we had to begin with. And it's all based on perspective.

Q. And you go on to say that "Lesser surgical techniques for SUI have lasted longer in common place surgical therapy than TVT-Secur. This does not mean that it was flawed in design or concept. It was not brought to market too quickly, it did not have high side effects. In my opinion, the TVT-Secur was a safe and effective therapy

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for SUI."

And my question is, what are you basing your opinion on with this respect? And I think we've touched on some of it, but I want to make sure I haven't misunderstood what was meant in this particular section, so I was going to get you to explain it to me.

A. So let's take, for instance, something -- injection therapy for incontinence. That's been around for years. Collagen, Coaptite, other things. It's nowhere near as effective as any of these procedures, but people still use it. It doesn't mean the product is flawed. It means that it does what it's supposed to do.

The same thing with TVT-Secur. It's designed for what it's meant to do. It has low side effects. It was brought out in a situation where we already knew what mini-slings can do, that, in my opinion, that it was brought in in a situation that was -- did not raise any eyebrows. People, once they got the hang of it, were doing well. My patients were doing well with it. I was upset when it was taken off the market. So it wasn't a design flaw. It was just the nature of kind of the environment at that time.

Q. And, again, that's based on your experience with the product and from a clinical standpoint and not based on your analysis of the design history files

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or your understanding of the industry standards and such as that we talked about before. Is that fair? And you can correct me in any of those ways. But what I'm trying to make sure of is you haven't changed your opinion from earlier in our discussions to now with regards to the design of the product.

MR. WALKER: Object to form.

A. So, yeah, I see what you're saying now. So, again, when it comes to a product that's on the market, does it do what it's meant to do, is the design that it was made for get the job done. I can comment on that, and I think it was.

What I can't comment on is how did it come to being, from that standpoint. You know, where did it come from to become the shape it was in, how did they decide what angle to make the points at, all those type things. I have no idea. But when it came to market and it was used and the study showed what it did, then I can comment that I felt if there was a design flaw, it would have been obvious.

Q. And as far as your opinion that it was not brought to the market too quickly, is that based on -- I guess what I'm -- let me start back over with that.

Are you aware of any documents or testimony in the review that you conducted prior to forming

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your opinions in this case as to whether or not there may have been additional steps or more studies that had to be performed before this product was brought to the market?

A. Yeah. So there was internal documents about should we do more studies or not, and the consensus felt that based on the previous TVT retropubic, TVT-O, the fact that the mesh was proven already and it was the same mesh, that they needed some studies to prove certain things, and that then it was up to the FDA to decide if that was adequate or not. And the FDA approved it, so you can only -- you have to go by that.

Q. And in your opinion it doesn't have high side effects. And that's based on the literature that you've read and your clinical experience with the products or the TVT-S devices that you've implanted. Is that what you're basing that on?

A. Yes, ma'am.

Q. And you're not aware of any studies that suggest that the side effects were any greater than the other devices, the TVT-R and the TVT-O?

A. If you look at the big studies, the randomized controlled trials and the big meta analysis studies, there's really not. You can see that now. You know, even after the Secur came off the market, they did some more studies afterwards, and you can see there's not a

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significant difference in severe side effects. The caveat would be whether there's a difference in efficacy, and I think there's a small difference in efficacy, but some studies show very similar efficacy.

So if you're talking about efficacy being a side effect, let's make sure to clarify that. That's not a side effect, I mean, that I would say is a significant side effect specific to that device. That can happen with any type of incontinence procedure. I think, if you're asking me, you know, erosion, extrusion, those type of things, those type of things are documented to be very similar.

Q. And I apologize. That's what I meant to do, was to distinguish between the safety issues and the efficacy. So you did very well in explaining that and the --

A. That makes me worry.

Q. With regard to the success rates, are you aware of any studies that suggest that there is a decline in its effectiveness the further out from this procedure that you get, or if it remains constant after the procedure?

A. Well, all the slings -- it's not specific for Secur, but all the slings, whether it be mesh or non-mesh, they do show a gradual increase in incontinence

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rates.

Q. And are you aware of anything particular to the TVT-S that suggests that the initial postoperative success was great, but there was a very quick decline in the effectiveness of --

MR. WALKER: Object to form.

A. I think I saw a study or two that may have commented on that. But, again, when you look back at the big overall picture, that doesn't really play out as much.

Q. Okay. So now we're to the TVT-O, TVT Secure warning section of your report.

A. And before we get started, can I take a bathroom break real quick?

Q. You sure can.

(Thereupon a break was taken from 1:04 p.m. to 1:07 p.m.)

BY MS. BAGGETT:

Q. So when we went off the record, we were about to start the section of your report on page 17 where you talk about TVT-O and TVT-Secur warnings. And I just want to clarify our discussions earlier with regards to the warnings.

Your opinion is based on your clinical practice and what you know as a surgeon and not necessarily on the regulations involved with the warnings and the

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obligations with reporting, such as that, or tell me, correct me, as to what your opinions will be.

A. My opinions are going to be based on clinical work, not bench work.

Q. And the next section on page 18, we talked about degradation. Is it fair to say that anything you read with regards to the topic of degradation would have been included in your reliance materials?

A. Yes.

Q. Okay.

A. Well, yes. I will say, though, that I tried to get a little bit more familiar with that term. And so there were some PubMed searches that I did that I just kind of perused the abstracts of. I didn't break down every bit of it. I just tried to learn a little bit more about what that was all about.

Q. But if it had an impact on or changed your opinions, that would have been something you would have listed in your reliance material?

A. Yes. Yes, ma'am.

Q. Cytotoxicity. We talked briefly about whether or not the mesh was inert. I just want to understand whether or not your opinions on cytotoxicity come, again, from your practice and experience with the mesh or if there's some underlying research or material

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that you reviewed that you're going to testify with regards to the more basic properties and such, like polymer science and things like that.

A. At this point I'm not planning on testifying as an expert in those bench type of issues. I know some about it, but not enough that I would feel that I can be -- I'm not going to be able to tell you how those polymers are put together. I'm not a chemist.

Q. And, let's see, with regards to contraction, your opinion with regard to whether or not mesh contracts once it's in the body, have you read any literature that suggests that the mesh contracts or shrinks over time?

A. The literature that I read suggests there's some initial foreign body reaction, and that can cause a kind of scarring which can cause that a bit. But when you actually look to see if it moves or contracts, there's no data on that at all. There were different studies to look at placement of the mesh. And the biggest thing, from my perspective, that proves it is if there was continued contraction, then we wouldn't see a worsening or a decline in incontinence rates. We'd see an improvement in incontinence rates and we'd see also an increase in retention rates, which we don't see.

So looking at different studies on whether

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the mesh actually moves, you know, could there be some slight contraction from the fibrotic reaction? Yeah, but not substantially, not clinically a large volume, a large percentage.

Q. Is it your experience that different patients scar differently in response to trauma?

A. I mean, there's very little change. I mean, it's all within a certain realm, yes.

Q. By that I mean like some people when we get a scar -- I was bitten by a dog and it's recessed. Some people develop these really thick ones.

A. Those are called keloids and some people have a problem with it. It doesn't occur vaginally that I'm aware of. From my understanding, it's only on the epidermis.

Q. So the tissue in the vagina is different than the skin in the way that it responds to --

A. Well, again, you're not going to see -- I've never seen keloids vaginally. You know, everybody heals a little bit differently, but not substantially differently.

Q. And based on the foreign body response, even if it's the initial healing process, does that affect the development of adhesions in the area?

A. Adhesions? There shouldn't be any

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adhesions.

Q. If we go to page 20, Section 4, pores too small, we discussed that earlier as well. Is your opinion different than what we discussed before as far as the studies that you've reviewed, the materials that you've looked at of the internal documents on pore sizes -- is there something about pore size that you are familiar with enough that you feel comfortable rendering an opinion as to the pore size and its effects on success of the procedure or any of the complications that may result from the procedure?

A. No. But Moalli is the paper that I remember referencing now as far as the pore size. But, no, I think I said everything earlier that I wanted to say.

I have a little bit of confusion because on one hand there's this concept of the mesh somehow pulling, but then there's also this concept of the mesh contracting. And so I feel like it's contradictory how -- I mean, I don't think either one of them will happen with any significance. So I think pores pretty well stay the same. And I can tell that's the case on the few pieces of mesh I've had to remove, there's really no clinical difference whenever -- a visible difference whenever you look at the mesh that you've removed when it's sitting there in the patient, you know, years after surgery verus

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when it was put in. I mean, it looks pretty well the same.

Q. When you review the mesh that you review, do you do so with the naked eye or do you look at it under a microscope?

A. Me personally, I look at it with the naked eye, but the pathologists look at it under the microscope.

Q. And are you aware of whether or not the pathologist that you send your mesh to does any type of analysis to determine whether or not the mesh has retained its pore size, original pore size?

A. Well, I don't -- no, ma'am, to answer your question.

Q. That's not part of your practice on a daily basis?

A. Yeah, they don't measure the pore size. But from a visible standpoint, you can tell it hasn't deformed.

Q. Section 5 where it says, "Mesh is too heavy, meaning lightweight mesh is preferred," you can go ahead, and if you will, tell me what your opinion is with regards to that.

A. Well, that was an interesting point. I mean, this whole thing has brought up some points. And I wanted to mention too that part of my being an expert witness means I have to follow the code of conduct of the

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American Urologic Association, which says follow all -- consider all sides of the point, don't just consider one point.

So, you know, this is an interesting concept that I've had to really deal with. But if you actually look at some of the data, I mean, it really is inconsistent, number one, and there's no consensus. I mean, this heavyweight versus lightweight thing, I don't understand -- I mean, I understand where your perspective is, but my perspective isn't the same. And a lot of this mesh was based on huge pieces of mesh that were placed in the abdomen, not a very small thin piece that was placed vaginally. And so I think that's comparing apples to oranges.

And, secondly, you can see here that in certain classifications, your describing of heavyweight mesh isn't necessarily what one classification stated that this mesh was. So I think there's a lot of inconsistency, but the main thing I came away with this is that the mesh is the appropriate mesh for what it does. The weight is the right weight.

Q. Do you have an opinion as to whether or not a mesh used for a hernia application would be appropriate for use in the female reproductive area based on, like we discussed before, the location of it and the

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dynamics, the difference between the dynamics of those two applications?
A. It could be, and let me tell you why it couldn't be. They used GORE-TEX for mesh repairs in the past. And then they tried to use that for female slings and it just didn't work. There was too many problems. And so that has been abandoned. But prolene and polypropylene is a different story.
Q. And if you look to page 21, laser-cut mesh versus mechanically-cut mesh, we talked about that briefly earlier. As far as your opinions here, you say that the mesh is not defective because of the way that it's cut. Can you tell us a little bit more about how you came to that conclusion?
A. Right. So if you look at studies from TVT-O, there's some TVT-O that's laser cut and some that's mechanically cut. Personally, I think if you polled most physicians, they wouldn't know the difference in what they were holding. But if you were to look at the studies to see if there was a difference, you're not going to find it. And so based on that, you have to then conclude that whether it's laser or mechanical cut, it's of no clinical difference. There's just no studies. There's nothing there to support it.
Q. As far as your review in preparing your

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opinions on that matter in this case, do you recall reviewing any documents, internal documents, from Ethicon that suggest that there was a concern --
A. Uh-huh.
Q. -- with regard to these differences and whether or not they actually did make a difference in the success rates or the safety profile of the product?
MR. WALKER: Object to form.
A. Yes, I do remember seeing internal documents and there were conversations. And I think those conversations had to be had because there was a difference. But, again, I'm looking at it from a perspective of is there any data to suggest there's a problem or a difference. And if there is, I'm not aware of it.
So conversations and those things have to take place within a company. I'm not worried about that. It doesn't change my viewpoint. And I actually applaud them for thinking outside the box. But I don't see that it's been borne out in any literature.
Q. If Ethicon were to become aware of the inferiority of a particular aspect of their product, would you expect them to take the steps necessary to fix whatever was making the product inferior in some aspect?
MR. WALKER: Object to form.
A. You know, in that situation, if you're

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describing a company trying to improve upon it, they already have, yeah, I would expect that.
MS. BAGGETT: I'll reserve the remainder of my questions, if necessary, for rebuttal.
(Time 1:20 p.m.)
EXAMINATION
BY MR. WALKER:
Q. Doctor, do you recall being asked questions about the issue of particle loss with respect to mesh?
A. I do.
Q. In the course of preparing your expert report, did you review the medical literature to determine whether or not there was any clinically significant issue with particle loss with respect to mesh?
A. I never came across that.
Q. Have you, in your experience, seen any clinically significant problems stemming from particle loss in mesh?
A. I have not.
Q. Do you recall being asked about cytotoxicity and degradation?
A. Yes.
Q. And those are issues that you address in your expert report, correct?

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A. Correct.
Q. Do you plan to offer an opinion about the biocompatibility of mesh?
A. Yes.
Q. And what is that opinion?
A. That it is biocompatible.
Q. And do you have an opinion as to whether or not mesh used in TVT-O and TVT-Secur is cytotoxic?
A. Am I going to give an opinion about that?
Q. Yes.
A. Yes, I am.
Q. And what is that opinion?
A. That it's not cytotoxic.
Q. And what do you base that opinion on?
A. My research, my personal experience, meetings, literature, all the things that come about. All these things have to be processed from a positive and a negative standpoint, and after reviewing that, that's my opinion.
Q. And you were asked a number of questions about degradation as well.
A. Yes, sir.
Q. Do you recall reviewing any internal company documents that dealt with the issue of degradation of prolene?

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A. Yes.
Q. And when you were forming your opinions in this case, did you consult the medical literature to determine whether or not degradation of prolene is a clinically concerning issue?
A. I did.
Q. And what is your opinion with regards to the degradation of mesh?
A. Well, I've never seen it degrade. I've never seen any studies that say it degrades, that it turns into nothing. So, I mean, there's really no data at this point.
Q. And have you reviewed medical literature that concludes that prolene does not degrade?
A. Yes.
Q. And did you rely on that literature when you formed your opinions?
A. Yes.
Q. You were asked a number of questions about polypropylene and then questions about prolene. Just so the record is clear, you understand that polypropylene is a component of prolene, correct?
A. Right. It's not just the prolene.
Q. And prolene is polypropylene plus the additives the company has put into it, correct?

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A. Correct.
Q. You were shown a number of internal company documents by plaintiff's counsel during today's deposition. Do you recall that?
A. Yes.
Q. As a pelvic floor surgeon, when you are looking to form opinions regarding a medical device, where would internal company documents rank on the spectrum of what sources of information you're going to give weight to?
A. Extremely low. Meta analysis, randomized controlled trials, everything in the case studies would be very high. Clinical experience is down a little bit lower and then below that would be internal company documents about conversations about the mesh.
Q. And why would you place internal company documents below those other sources of information?
A. Because those are opinions. There's no facts. I mean, if there is facts, they haven't been -- if there's any shred of a fact, they have to prove it somehow, and those opinions just don't -- are just case-specific opinions.
Q. So you would agree that internal company documents are not what we would call Level 1 evidence?
A. Yes.
MS. BAGGETT: Object to form.

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Q. And would you agree that internal company documents lack the benefit of the creative process that you're going to find in medical literature?
A. Correct.
Q. The Tips & Tricks document came up a number of times in the deposition. Do you recall that?
A. Yes.
Q. And do you recall seeing internal company documents that demonstrated that Ethicon disseminated that information to surgeons regarding the TVT-Secur?
A. Yes.
Q. And is that a document or are those documents that you relied on when you formed your opinion about the adequacy of Ethicon's professional education with respect to TVT-Secur?
A. Yes, that was part of it. I saw that they were making an effort to improve upon what was already going on.
Q. You were asked some questions about the pore size, specifically affected porosity. Do you recall that?
A. Yes, sir.
Q. And when you were forming your opinions in this case, you considered the issue of the pore size of the mesh, correct?

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A. I have to.
Q. And did you review the medical literature with an eye towards forming your opinions regarding the adequacy of the pore size of the mesh?
A. From what I could, yes, sir.
Q. In your review of the medical literature, did you see any evidence that the physiological forces applied to the mesh will deform its shape in such a way that the pore sizes are compromised in a clinically concerning way?
A. Not physiologic forces, no.
Q. Are you aware of any objective medical evidence or medical literature that has found that the pore size of TVT-O or TVT-Secur mesh, once it's been implanted in the body and integrated into the tissues, becomes inadequate or too small?
A. I never came across that.
Q. You were asked some questions about the weight of the mesh and the existence of other lighter-weight mesh materials. Do you recall that?
A. Yes.
Q. Do you recall reviewing company documents regarding a project TOPA?
A. Yes.
Q. What was this project TOPA?

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A. TOPA stood for transobturator. That was partially what it was. So they were looking at a lighter-weight mesh for incontinence.
Q. And were the company's efforts with respect to developing a lighter-weight mesh to treat incontinence successful?
A. No. No, they failed miserably.
Q. In fact, they failed six cadaver labs, correct?
MS. BAGGETT: Object to form.
A. Right.
Q. And does the fact that the company failed in its efforts to develop a lighter-weight mesh to treat incontinence, is that something that you considered when you formed your opinions about the feasibility of a lighter-weight mesh to treat SUI?
MS. BAGGETT: Object to form.
A. Again, we've got to go back to lightweight and heavyweight, and that's a little bit confusing to me. But in response, they did try to come up with a different type of mesh. But, yeah. So that definitely made me realize that just because something is "lighter weight" doesn't necessarily mean it's better for that particular situation.
Q. You were asked some questions about the

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complication rates of TVT-Secur relative to other slings. Do you recall that?
A. Yes, sir.
Q. And I believe you testified that the medical literature essentially showed similarity in complication rates between Secur and other slings like TVT-O; is that correct?
A. Right.
Q. Did you see in your review of the literature any findings that the laser cut quality of TVT-Secur was causing any increase in erosions or other complications?
A. That wasn't something that I came across. I never saw that mentioned.
Q. And you looked at a number of studies dealing with TVT-Secur and TVT-O, correct?
A. I looked at hundreds and hundreds of studies.
Q. If I could direct your attention to tab 50 of what was marked as Exhibit Number 7. You were asked about a statement in your report concerning the other professional societies that were endorsing this AUGS/SUFU position statement. Do you recall those questions?
A. I do.
Q. Do you see -- in tab 50, just so the

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record is clear, that is what?
A. Tab 50 is the American Urologic -- or the American Urogynecologic Society and SUFU Position Statement.
Q. And this is a position statement that you read and relied upon when forming your opinions?
A. Right.
Q. In fact, you referred to it in your expert report.
A. Exactly. Yes, sir.
Q. And then at the end of this position statement, does it lists these organizations that were endorsing that statement?
A. It does.
Q. Which ones? Which organizations endorsed the AUGS/SUFU position statement?
A. The American Association of Gynecological Laparoscopists, the American College of Obstetricians and Gynecologists, the National Association for Incontinence, the Society of Gynecologic Surgeons, and Women's Health Foundation.
Q. Doctor, you were asked a number of questions about warnings and the requirements for what belongs in an IFU.
Am I correct that you intend to offer

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opinions regarding what is commonly known amongst pelvic floor surgeons in terms of potential risks and complications associated with vaginal surgery?
A. Yes.
Q. And in terms of having an opinion about what risks or complications would be commonly known amongst pelvic floor surgeons, what would you base your opinions on?
A. What is commonly known? Well, textbooks, journals, personal experience, clinical trials, those type of things.
Q. And that would be true with respect to all of the potential risks and complications that you address in your expert report; is that correct?
A. I do. Yes, I do. There are -- a lot of the aspects of what you're describing are things that are general complications that can occur with any pelvic surgery. Are there some that are specific for mesh? Yes. We already know those are accepted known side effects. Okay? But anybody who performs pelvic surgery is aware of all of those to begin with.
Q. Doctor, are all of the general opinions that you intend to offer regarding TVT-O and TVT-Secur contained either in your expert report or in testimony that you've provided today?

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A. As of now, yes.
Q. And are all of those opinions based on your education, training, experience, review of the medical literature?
A. Yes.
Q. Do you offer all of these opinions to a reasonable degree of medical certainty?
A. I do.
MR. WALKER: That's all I have, Doctor. Thank you.
MS. BAGGETT: Very quickly, just a couple of things.
(Time 1:34 p.m.)
EXAMINATION
BY MS. BAGGETT:
Q. Now, in the questioning by defense counsel you were asked about particle loss and whether or not it's had a clinically significant impact on patients that you've treated. At least that's the way I understood it. You can correct me if that's wrong.
But my question is, have you been trained in pathology or do you perform any activities involving analysis of pathological specimens?
A. We have been trained in pathology as part of our residency training and part of the testing that we

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have to do when we get out of residency. As far as the day-to-day processing of it, no, but it is something that we will oftentimes go to the pathologist and review slides and discuss things with him, go to tumor conferences, other things where we have to discuss pathology and review pathology.
Q. In your normal course of practice, is it your habit to review the pathology that you remove from your patients for any signs of particle loss or the impact that it may or may not have on it? Is that something that you do routinely in your practice?
A. That's something that nobody does routinely, ma'am.
Q. And you have not undertaken any efforts to study whether or not there is particle loss and whether or not that particle loss has any clinically significant impact on the outcomes of the patients who were implanted with the device, have you?
A. So you're asking me if I've looked at any studies based on particle loss?
Q. No. No. It's even simpler than that. Have you conducted any studies or analyses and are you involved in any study that looks at the pathology of removed mesh devices to determine whether or not particle loss is something that happens, that occurs and whether or

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not it's clinically significant?
A. I'm not involved in a study of that nature.
Q. You were asked about ranking the importance of information that you relied on in determining your opinions in this case, and with respect to the internal documents, obviously, they are not Level 1 evidence like a study would be, but do the internal conversations and recordings of the device manufacturer that place a product on the market have any bearing -- any insight that you can glean from the development of that product and the company's understanding of that product?
MR. WALKER: Object to form.
A. That would be something that -- no, I cannot tell from just those company documents what their next step would be. What I can tell you is when I see company documents like that, it just tells me that the company is always reviewing what's going on. And I wouldn't anticipate, even if they were doing -- whether the product they feel is doing perfectly or there's some improvements on it, I would anticipate internal documents to try to comment on things they can continue to improve on. And whether that has -- you know, those things have no basis as far as what actually happens with the patients and the clinical data, all of that. So it's something we

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consider, but it's to be expected I would imagine.
Q. Does the review of those materials, the company documents, play a role in completing the picture of your understanding of the development of the device and an understanding of the appropriateness of the device for the application that we are here today about with regards to the pelvic anatomy of a women?
MR. WALKER: Object to form.
A. It's part of the equation, yes, ma'am.
Q. And you were asked about the Tips & Tricks and the fact that Ethicon attempted to disseminate that information to the doctors.
Do you know if the dissemination of that document was limited in any way to certain groups of doctors or if it was provided across-the-board to anyone who --
A. I can't recall.
Q. And do you know if Ethicon undertook efforts to make sure that everyone implanting the device was provided with that information?
MR. WALKER: Object to form.
A. I do recall that there was an effort, concerted effort. I don't know. I can't recall the document, but I do remember there was an effort to say we need to get this out to the physicians out in the field.

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Q. But you're not aware of whether or not that information was limited to any particular group of doctors. You feel that it was disseminated to all doctors equally.
A. I can only say -- and I can't say whether it got to all doctors or not.
Q. Okay. You were asked questions about TOPA, and we didn't go over that so I'm just going to ask you a couple of questions about that.
And I think you stated that you understood that TOPA was an attempt to evaluate a lighter-weight mesh for the applications similar to the devices we're looking at today. And I think you said that it was unsuccessful because the mesh was too stretchy or too -- you tell me. You said it was unsuccessful because --
A. I said it was unsuccessful. I didn't say why.
Q. Okay. And what is your understanding of why it was unsuccessful?
A. It wasn't strong enough.
Q. And have you reviewed the deposition testimony in this litigation regarding that study?
A. I think I reviewed bits and pieces of it, but that's been many months ago, and I couldn't quote any of it right now.

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Q. And do you know how many, if any, documents that you reviewed related to that study other than the study itself?
MR. WALKER: I'm sorry. By "study," do you mean just the project TOPA itself?
MS. BAGGETT: Right. I'm sorry. Yes, TOPA.
THE WITNESS: I would say that I reviewed five to ten documents, if that. I don't recall. It wasn't a large volume.
BY MS. BAGGETT:
Q. And do you know what project SCIOM was, spelled S-C-I-O-M?
A. That is -- I do remember reading about it, but the details of it escape me right now.
Q. Did you read any deposition testimony regarding that as well?
A. I probably did, but I don't recall.
Q. And do you know what project Matrix is?
A. No, ma'am.
Q. Did Ethicon ever submit a 510(k) submission -- are you aware of whether or not a 510(k) submission was submitted for the SCIOM?
A. I'm not sure.
Q. And the same question with regard to the

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Matrix.
A. I don't know anything about Matrix.
Q. And do you know if a 510(k) was ever submitted on TOPA?
A. I don't know.
Q. If Ethicon's expert testified project SCIOM was killed for business reasons, would you disagree with that?
MR. WALKER: Object to form.
A. I don't remember.
Q. If Ethicon's employees testified that the project Matrix was killed for business reasons, would you disagree with that?
MR. WALKER: Object to form.
A. Again, I don't recollect anything about that.
Q. And the same with regard to TOPA?
MR. WALKER: Object to form.
A. From TOPA's standpoint, that just didn't work, and after a while I think they realized that was something they needed to abandon and maybe revisit for another day. I don't know the reasons for that, though.
Q. Did you ever review any of the cadaver labs for TOPA?
A. Yes, I do remember vaguely. I don't

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remember any of the details, ma'am.
Q. Did you talk to any of the engineers or doctors who worked on any of those projects?
A. No.
Q. Do you know what the size of the mesh in TOPA was?
A. I can't recall.
Q. Do you know what the pore size was?
A. I can't recall.
Q. Do you know what the weight was?
A. No, ma'am.
Q. Do you know what type of material was used?
A. That would be a guess. I shouldn't answer that. I don't know for sure.
Q. And the same questions with regard to SCIOM and Matrix. If you want me to go through them all, I will.
A. No, ma'am. I don't remember.
Q. You were asked about the AUGS position statement and you went to it. You were asked to go to it in your notebook. Is that tab 50?
A. I believe that's right.
Q. And I just wanted to bring back the document we looked at earlier today that I had referenced

was Bates stamped MIL00268. And I just want you to take a look at it and see if that refreshes your recollection as to whether or not that is similar to or in any way related to the document that you referenced in your testimony.

A. Okay.

Q. And other than the fact that I've represented to you that that document, with the edits on it, was produced in this litigation through the production requests, did you review anything in preparing for your deposition today or preparing for this report that you drafted as to whether or not Ethicon had anything to do with the editing and/or drafting of this position statement that was produced through AUGS and SUFU?

MR. WALKER: Object to form.

A. Ma'am, I have no idea. This is just one document. I have no idea if it was -- it doesn't tell me where it came from, who edited it. There's just not enough information for me to really comment on that. I don't know.

Q. And that's kind of what I was asking. Based only on my representation that this was produced by Ethicon, you've not read anything in the materials that suggested that Ethicon had anything to do with the drafting or publishing of this document?

A. I'm not aware of any.

MS. BAGGETT: That's all I have.
MR. WALKER: Nothing further.
(Signature waived.)
(Time 1:47 p.m.)

C E R T I F I C A T E

STATE OF TENNESSEE)
COUNTY OF KNOX)

I, Charlene M. Shade, LCR and Notary Public, do hereby certify that I reported in machine shorthand the deposition of BRIAN PARKER, M.D., called as a witness for all purposes applicable; that the said witness was duly sworn by me; that the reading and subscribing of the deposition by the witness was waived; that the foregoing pages were transcribed by me and constitute a true and accurate record of the deposition of said witness.

I further certify that I am not an attorney or counsel of any of the parties, nor an employee or relative of any attorney or counsel connected with the action, nor financially interested in the action.

Witness my hand and seal this the 3rd day of April, 2017.

_____
Charlene M. Shade, LCR
Notary Public
Tennessee LCR #105

My Commission Expires: 7-6-19